Booster

Powered by Kalogon™

Whitepaper

Table of Contents

Abbreviations

ACB - Air Cell Based
AMS - Air Management System
ASS - Ambient Sensing System
APAM - Alternating Pressure Air Management
DI - Dispersion Index
US FDA - Food and Drug Administration
IT - Ischial Tuberosity
PI - Pressure Injury
PPI - Peak Pressure Index
SCI - Spinal Cord Injury
MAUDE - Manufacturer and User Facility Device Experience, a U.S. database of medical device reports
MDR - Medical Device Regulation

Definitions

1. **Single-chamber vertical air cell cushion**: A synthetic rubber or injection molded plastic wheelchair cushion composed of numerous "fingers" which fill with air to support the weight of the user. Such a cushion is placed atop a wheelchair to reduce the interface pressure felt by the user when seated.
2. **Interface Pressure**: The pressure resulting from the force of a person sitting on a surface against the person's buttocks.
3. **Kalogon Air Management System (Kalogon AMS)**: The pressure controller apparatus and mechanical sub-systems employed by Booster and Sentinel, Powered by Kalogon.
4. **Sentinel**: Marketed as Star Sentinel Powered by Kalogon. This is the co-branded variant of Booster by Kalogon sold by ETAC AB and manufactured by Kalogon Inc.
5. **The Device/The Product**: Short-hand for the Kalogon Air management System
6. **Kalogon Inc.:** The manufacturer, design and intellectual property owner of the device and all device derivatives.
7. **Bottom-out:** Phenomenon seen in vertical air-cell cushions when such a cushion is inadequately filled with air when the user sits on the cushion. This results in the user's pelvis and bony prominences sinking through the cushion until contact with the base of the seat or wheelchair is made. Bottoming out can create very high interface pressure against the bony prominences of the user, and increases risk of pressure injury.
8. **Bony prominence:** Areas of a person's skeletal structure that experience high interface pressures when lying down or sitting down due to low surface area and decreased thickness of overlying tissue. Concerning wheelchair seating, parts of the femurs, pelvis, and coccyx (tailbone) are commonly involved.
9. **Class I Medical Device:** Per FDA (Food and Drug Administration) in the US and the MDR in the

EU, a Class I medical device is considered to present a low-risk to user/patient safety. In the EU, these devices are further divided into additional categories of regulatory requirements if such devices are sterilized or measure a vital sign or bodily function.

10. **Dispersion index (DI)**: Ratio between pressures applied within a bounding box and the entire seated surface. For the purposes of evaluation, this bounding box is placed around the ITs and sacrum as a means of comparing pressure applied in this region to the entire seated surface. Generally the lower the DI value, the more effective a cushion performs at distributing pressure away from bony prominences.
11. **Peak Pressure Index (PPI):** Average of pressures within a bounding box. Useful for evaluating generalized areas of higher pressure seen on a pressure map. The higher the PPI (consistently above 60 mmHg) the higher the pressure in the bounding region and vice versa.
12. **Two-finger method** / **Hand-check**: a clinical technique used to properly adjust air cushion inflation, where after initial overinflation and patient seating, the clinician places two fingers under the patient's ischial tuberosities and vents or pumps the cushion until the fingertips can barely move, ensuring optimal pressure distribution.

Special notes

- This paper uses the term *single-chamber vertical air cell wheelchair cushions* to refer to *single-cell or single compartment air based wheelchair cushions.*
- *This paper uses Pressure Injuries interchangeably with Pressure Ulcers*

Introduction

Pressure injuries (PI) are defined as localized areas of damage to the skin or internal tissue that occur due to prolonged exposure to mechanical forces, such as body weight or contact with medical devices, especially over bony prominences (Bharucha et al, 2018; Gefen et al., 2022; Lustig et al., 2021). Pressure injuries can significantly diminish one's quality of life, causing extreme pain and discomfort, and hindering the ability to perform activities of daily living (ADLs). PIs also lead to extended hospitalization periods, with Graves et al. (2005) reporting a median increase of 4.31 days in length of stay for patients with PIs. Patients with PIs have also been shown to have twofold higher risk of death compared to those without (Song et al., 2019). Approximately 60,000 patients die annually as a direct result of pressure injuries (Agency for Healthcare Research and Quality, 2014). The impact of PIs extends beyond physical symptoms, as patients often experience psychological effects such as humiliation, social isolation, and loss of autonomy (Qian et al., 2024). Additionally, PI treatment is extremely expensive. The cost for treating a single PI ranges from $20,900 to $151,700 (Padula et al., 2011). As of 2009, the national annual expenditure for PI treatment was $11 billion, a figure that has likely increased due to rising healthcare costs (Agency for Healthcare Research and Quality, 2014).

According to Mondragon and Zito (2024), every year an estimated 1 to 3 million people in the United States are affected by PIs. Vanderwee et al. (2007) conducted a study investigating the prevalence of pressure injuries in 5 European countries: Italy, Sweden, Belgium, UK, and Portugal. They found that the prevalence of PIs across 25 general and university hospitals in the five countries was 18.1%, with the sacrum being the most common site for PIs. Another study by Moore et al., (2019) conducted a systematic review of 79 articles on PI prevalence in Europe, and found that median prevalence was 10.8%, with the highest and lowest PI prevalence being in the Netherlands and Finland, respectively. Similarly, the sacral region was also found to be the most common site for PI development. Risk factors for developing PIs include immobility, reduced blood perfusion, and lack of sensation, just to mention a few. Approximately 95% of individuals with Spinal Cord Injuries (SCI) face a heightened risk of developing pressure injuries due to the convergence of impaired sensation, impaired mobility, and impaired circulation (Cook et al., 2020).

Wheelchair users particularly face an increased risk of pressure injuries (PIs) due to extended periods of seated immobility without pressure relief, compared to the general population (Vecin & Gater, 2022). While seated, body weight and external forces from support surfaces are concentrated on small areas around bony prominences, such as the ischial tuberosities (IT), sacrum, coccyx, and greater trochanters (See Figure 1). These areas are particularly susceptible to pressure injury development (Bharucha et al., 2018; Vecin & Gater, 2022). To alleviate pressure, wheelchair users are advised to perform offloading techniques (e.g. leaning over to one side or leaning forward as if to reach for an object on the floor the loaded areas) promoting blood flow and tissue perfusion (Vecin & Gater, 2022). Additional factors contributing to an individual's susceptibility to pressure injuries include shearing, friction, microclimate, unique anatomical bone structures, impaired sensory perception, tissue thresholds, and repair capacities (Gefen et al., 2022; Grey et al., 2006).

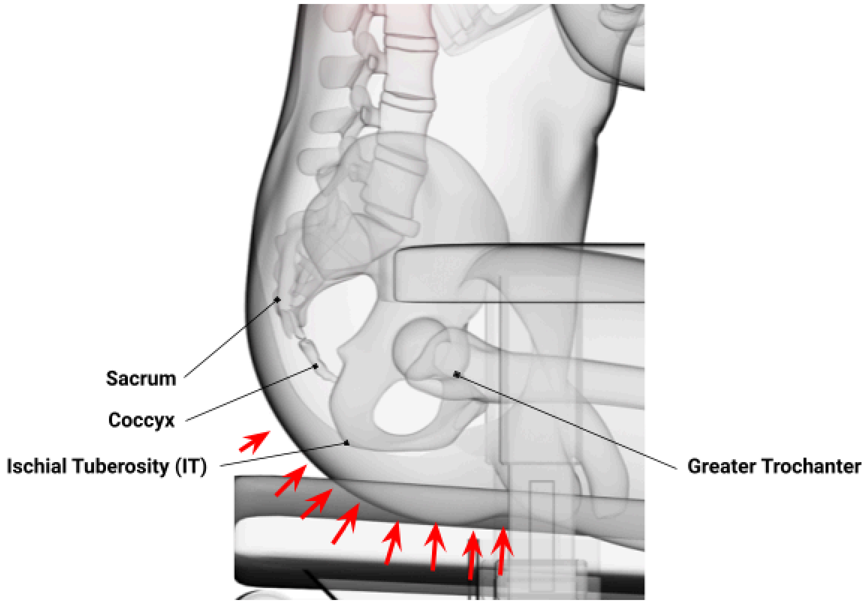

Figure 1: Internal structure of the pelvis, femur, and where pressures are applied by the seat when properly seated.

The risks faced by wheelchair users underscore the need for cushions that can alleviate the pressure in the sacral, IT, coccyx and great trochanter regions, and reduce the risk of PI development. Levy et al. (2014) found that Air-Cell Based (ACB) cushions, compared to standard foam cushions, performed better at lowering peak tissue stresses. Levy et al. (2014) suggested that this could be attributed to ACB cushion’s ability to facilitate immersion of the buttocks which creates a large load transfer area. Air-cell based cushions were also found to be useful for dealing with the effects of chronic Spinal Cord Injury (SCI). These air-cell based cushions provide pressure redistribution by increasing the surface contact area, primarily through mechanisms such as immersion and envelopment. Immersion gauges how deeply an individual sinks into the cushion, while envelopment assesses how closely the cushion conforms to the body's contours. The overarching goal is to reduce pressure points and minimize the potential damage to skin and tissues.

Following these developments, various air-based cushions have entered the market. Technologies such as Alternating Pressure Air Mattresses (APAM) and alternating pressure air cushions have proven effective for both preventing and treating pressure injuries (PIs). A common type is the single-chamber vertical air cell wheelchair cushion (e.g. Roho Standard/Hybrid single-compartment and Star standard single chamber air cell cushions).

These devices facilitate pressure relief, enhancing blood perfusion in loaded areas (Gefen, 2018; Vanderwee et al., 2007). Air-based cushions provide necessary comfort while allowing clinicians to adjust air-cell pressure to meet individual patient needs.

Limitations with Air-based cushions

As research continues to uncover the benefits of air-based cushions and their technological improvements for pressure injury care, users have reported some issues in their use. It is widely acknowledged that these cushions often suffer from leaks or under/over inflation due to environmental changes or other external factors such as weight gain or postural change over time. A search for air-cell cushion failure from the US Food and Drug Administration's (FDA) Manufacturer and User Facility Device Experience site (MAUDE) - which is a database of medical device reports of adverse events, specifying the device, patient problems and Manufacturer's responses - identified about 30 different reports of leaks with some of the air-based wheelchair cushions in the market from 2020 - 2024, demonstrating that this is a commonly referenced issue (Link to MAUDE cite). Additionally, a number of reviews on platforms such as Reddit and instagram, demonstrate some of the frustration users have with air-cell based cushions in the market, particularly for the maintenance demand and leaks (See Table 1).

Cushion leaks can result in "bottoming out," where the cushion deflates to the point that the ischial tuberosities (ITs), sacrum, and coccyx are exposed to excessive pressure, increasing the risk of PI development. Many wheelchair users who may use air-based cushions lack sensation in their extremities and as such, are often unaware that they have bottomed out and unable to feel the increased pressure on their bodies. The inability to be aware of cushion leaks creates anxiety among users, as leaks can occur unexpectedly and often when assistance is not readily available to replace the cushion. Stephens and Bartley (2018) further highlight that air-based cushions require user education to maintain air inflation level, regular maintenance to maintain correct operation, and have the risk of getting punctured. These three key maintenance concerns further increase the concerns that users may have when using an air-based cushion.

Maintaining the pressure recommended by clinicians is another key maintenance activity in owning and using an air-based cushion. Although designed to maintain recommended pressure once set, exposure to various ambient environments, such as high altitudes, use in aircraft cabins, hot/cold air etc, can affect the cushion's inflation level, potentially resulting in under/over inflation. An article in the New Mobility magazine discussing tips for flying with a wheelchair highlights that air-based cushions expand at altitude, affecting their inflation levels (New Mobility, n.d.). Moreover, resetting the cushion to the correct pressure often requires the use of a hand pump and/or access and ability to turn the vent valve, both of which may be inaccessible for users with certain conditions. Consequently, these cushions frequently require intervention from clinicians or trained individuals to ensure appropriate pressure is maintained *after* the user has already been exposed to an incorrectly inflated cushion for hours, days or weeks at a time. Park and Lee (2019) conducted a case study of two wheelchair users with spinal cord injuries, assessing the effects of seating education and cushion control. They demonstrated that measurement and control of air pressure in cushions were crucial for promoting a good posture alignment, reducing the risk of PI development in SCI patients. This emphasizes why leaks and constant air pressure management are crucial to creating an environment capable of effectively redistributing a wheelchair user's interface pressure against their cushion: a key element in reducing the risk of pressure injury development.

Customer complaints when common air-based cushions		
Platform	**Problem Type**	**Consumer Review Excerpt**
FDA MAUDE	Deflation	*"Customer claims that he developed a stage 4 pressure sore due to the cushion going flat..."* (Link)
FDA MAUDE	Deflation	*"Customer claims that she developed pressure sore and cellulitis due cushion going flat.Customer claims she sought medical attention at urgent care and wound clinic.."* (Link)
FDA MAUDE	Deflation	*"The customer alleged that cushion going flat contributed to pressure injury...."* **Manufacturer Narrative:** *"The cushion associated with complaint was returned and an evaluation report is attached.Evaluation of the cushion revealed a small laceration likely caused by an external force.."* (Link)
FDA MAUDE	Overinflation	*"Customer claims that he developed a pressure sore due to using cushion in an overinflated state ..."* (Link)
Reddit	Ambient changes	*"I always seem to have a problem with the cushion not holding air after I've taken a plane trip. A couple weeks after, it seems like they always go flat and won't hold anything..."* (Link)
Reddit	Maintenance of inflation	*"They are just leaky by nature. When properly inflated they are great. Chasing the optimal pressure is a giant pain. Worst cushion I ever had and it was so terrible I threw mine away when I replaced it."* (Link)
Reddit	Leaks and Maintenance costs (Constant need for	*"Hi, my partner is a permanent wheelchair user. Her ROHO air cushion started losing air long ago, and after many attempts to patch it, we think it's time for a new one.....We*

	repair)	*could not find the same size on Amazon. Besides, ROHO seems to be selling their cushions for about $400 - which is too much for us at the moment as an out-of-pocket expense."* (Link)
Instagram	Leaks and Maintenance costs (Constant need for repair)	*"Don't let a hole in your game deflate you, patch it and keep rollin! This is the seat cushion I use in my saddle to avoid getting sores when I ride. As you can tell I have to patch it quite often because it gets pin holes and goes flat while I ride. Was sitting here patching a hole and made me think… Don't let a hole keep you from chasing your dreams, desires, and passions. Patch it up and keep trying!"* (Link)

* Links to specific reviews are in the review column, marked as 'Link'

Table 1: Excerpts of customer complaints with air-cell based cushions in the Market

Amidst this landscape *Kalogon's Booster*™ was developed to serve as a solution to enhance the effectiveness of air-based cushions, addressing critical risk factors such as cushion leak detection, leak mitigation, adaptability to weight changes, and ensuring inflation-level stability over prolonged durations. The goal of Booster is to help maintain the pressure of a *single-chamber vertical air cell wheelchair cushion* as set by a clinician. The device also provides alerts for cushion air-leaks and will maintain the set pressure over time as the user's weight changes or ambient conditions fluctuate.

Booster by Kalogon

Booster is an air management system designed as an accessory for single-chamber vertical air cell *wheelchair cushions* to maintain the air inflation level, which is set by a suitably experienced person or clinician to suit the individual's weight, body shape, and pressure redistribution requirements. It is designed for wheelchair users and others assessed as requiring a single-chamber vertical air cell wheelchair cushion. This is typically for individuals who are at risk of pressure injuries. There is no minimum/maximum user weight limit, provided the user is within the set weight limit and size requirements for the connected cushion as determined by the cushion manufacturer. Booster is a Class I medical device as defined by the European Union (EU) Medical Device Regulation (MDR) 2017/745 and by the US FDA with Regulation Number 890.3920 . Booster is designed to be a safe and low-risk device for users.

Purpose

The Device is intended to maintain the internal air pressure of a single-chamber vertical air cell cushion as set by a suitably experienced person. It is designed for use in a Home Healthcare

Environment and intended to be used in indoor and outdoor environments in conjunction with a compatible single-chamber vertical air cell cushion.

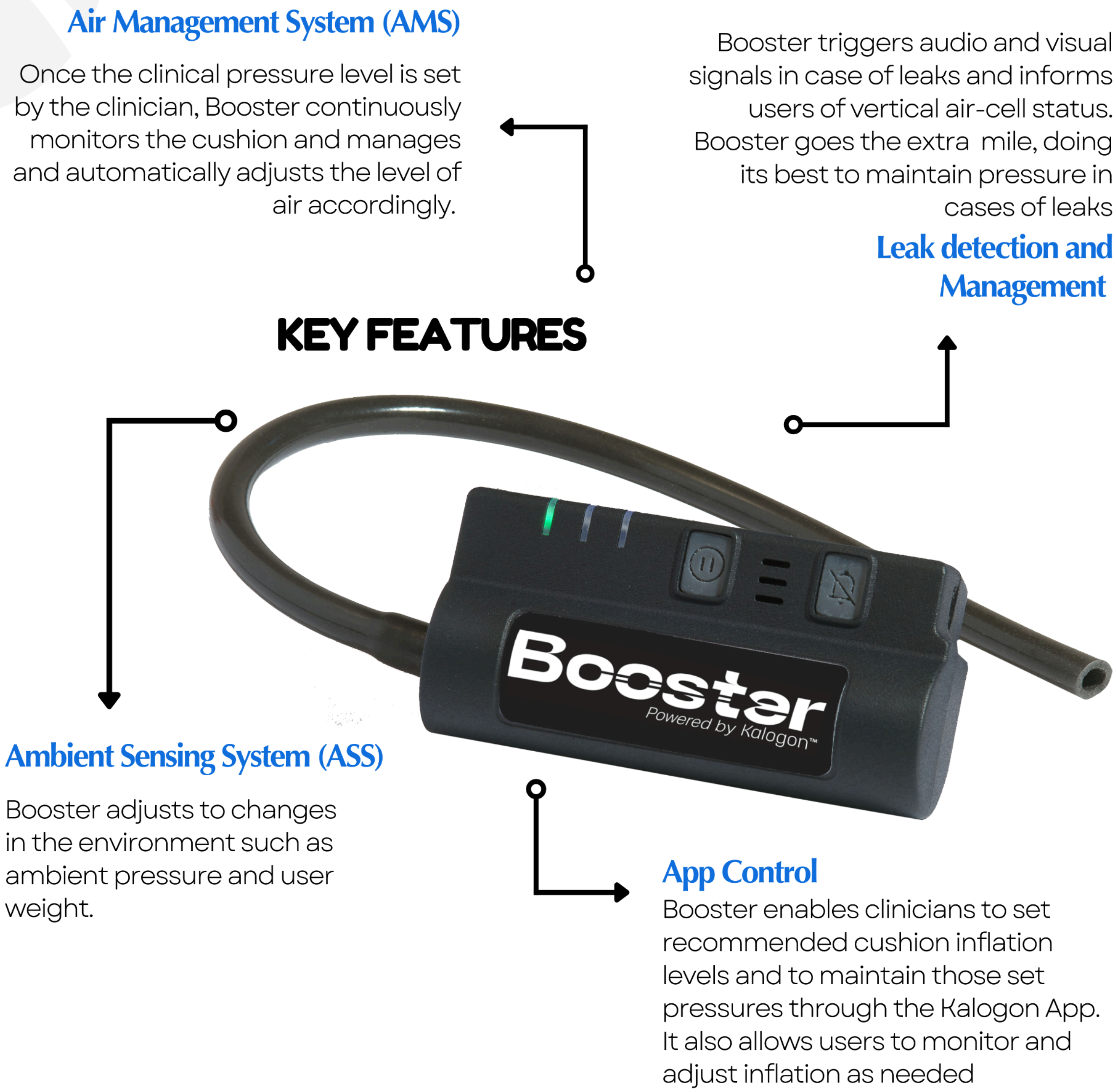

Figure 2: Booster by Kalogon and Special features

Special Features

Air Management System (AMS)

Booster is a controller that enhances most existing vertical air cell cushions to control and maintain pressure set by a clinician. Once the clinical pressure level is set by the clinician, Booster continuously monitors the cushion and automatically adjusts the level of air accordingly.

Ambient Sensing System (ASS)

Booster continuously monitors and adjusts the cushion's air-inflation volume in response to various factors. These factors include changes in user posture, fluctuations in applied weight (such as when placing objects on one's lap during daily activities), gradual or sudden bodily weight changes, and even ambient conditions like altitude or weather (i.e. hot and cold weather) that can affect air pressure.

This adaptive capability is crucial as most air-based cell cushions do not account for these variables, which could result in over/underinflation of the cushion. Without adjustment, these changes could lead to cushion deflation or, in extreme cases, bottoming out. Booster addresses this issue by dynamically maintaining the cushion's inflation at the clinician-set level, ensuring consistent pressure redistribution and user comfort. Whether the user gains weight over time, lifts something heavy, or travels to a different altitude, Booster works silently in the background to maintain optimal cushion performance.

Leak Detection and Management

Booster's advanced leak detection and management abilities are designed to ensure user safety and expected cushion performance in the presence of changing ambient and user conditions. Booster continuously monitors air pressure within the cushion, and is capable of identifying leaks ranging from small punctures or shear-induced tears to substantial air loss situations. When a leak is detected, Booster promptly triggers both audio and visual alerts, ensuring timely awareness of the problem. Beyond detection, Booster actively pumps air into the cushion to maintain optimal pressure within the cushion, regardless of the leak's severity. This proactive approach helps to preserve the cushion's pressure redistribution function, even in cases of air loss. Booster's robust system strives to maintain cushion integrity and user comfort until repairs can be made, providing an added layer of safety and reliability for users in their daily activities.

App Control

Booster empowers clinicians and end-users with a degree of customization over their seating experience. Through the user-friendly Kalogon app (available on Google Play Store and Apple App Store), clinicians can set recommended cushion inflation levels, while individuals can fine-tune their cushion's air pressure to their preferred firmness, all without the use of a manual hand pump. This control allows clinicians and users to adjust the pressure distribution, finding the perfect balance between support and comfort for their unique needs. Once the new pressure level is set, Booster will work to maintain the correct air cushion at that level.

How it works: Kalogon Air-Management System (Kalogon AMS)

Booster operates through a sophisticated pressure monitoring and adjustment system. More than once a second, it samples the pressure within the cushion and compares it to the set point established by either the user or clinician via the app or clinician mode. If the system detects a deviation from the set point, it automatically adjusts the pressure, either by inflating or deflating the cushion as needed.

If Booster detects that multiple pumps per minute are needed to maintain a set pressure level, it may indicate a leak, prompting the device to alert the user. If Booster registers that a leak is likely, a red light is activated and an audible alert is given to notify the user. This continuous monitoring and adjustment process also accounts for changes in ambient pressure. For instance, during air travel, as cabin pressure decreases during takeoff, the relative pressure in the cushion increases, which can cause the cushion to become overinflated. Booster responds to this by venting air to maintain the desired pressure. Conversely, during landing, as cabin pressure increases, the relative pressure in the cushion decreases, and Booster adds air to the cushion.

This automated pressure management eliminates the need for manual adjustments via hand pumps or using the cushion valve to relieve pressure, ensuring consistent and appropriate pressure levels across various environments and situations. Booster's ability to maintain a stable set point through constant measurement and adjustment is the core principle of its operation, providing users with a reliable and adaptive seating solution.

Booster Validation: Feature evaluation

A series of tests were conducted to evaluate Booster's performance on single-chamber vertical air cell wheelchair cushions, focusing on its response to leaks and weight changes. The goals of these tests were to assess Booster's ability to:

- Detect and respond to small leaks, simulating everyday wear and tear
- Manage large air loss scenarios, mimicking significant cushion damage
- Adjust to sudden and gradual weight changes during typical use

These tests aimed to verify Booster's claimed features across various cushion types, including the Standard and Hybrid single-compartment ROHO cushions and the Star StandardAir and StabilAir cushions. The goal was to ensure Booster's effectiveness in maintaining proper cushion inflation and pressure redistribution under different conditions.

1. Small Leak Tests

Methodology

The small leak tests for Booster simulated real-world scenarios of cushion damage. The

Kalogon team created controlled leaks in test cushions and observed Booster's response. These intentional tears mimicked shear-induced tears that naturally occur over time in air-based cushions due to users' transfers (See Figure 3). Two primary test procedures were employed: a *Duration to Alarm test* to measure leak detection speed, and a *Leak Management Test* to assess long-term inflation maintenance in the presence of active leaks in the cushion. The team collected pressure mapping data, comparing the Dispersion Index (DI) and Peak Pressure Index (PPI) of the tester on a leaking cushion with and without Booster connected.

At the start of the tests, the tester's ischia were acceptably immersed in the cushion and checked using the two-finger method. The tester then sat on the cushion for 1 hour and every 3 - 5 seconds the device triggered to pump as it sensed a drop in air pressure due to the leak. At the end of 1 hour, the two-finger method was again conducted to ensure that the tester's ischia remained properly immersed. After concluding the test with Booster connected, we disconnected the controller and closed its relief valve port to evaluate the leak's severity on user immersion. The team then measured how long it took for the cushion to go from passing the two-finger method to bottoming out, simulating what would happen if a wheelchair user stopped using the device on their damaged cushion.

Figure 3: **Test cushions with small tears created per test-plan.** The defining criterion for A small leak was *an air loss event generated from a hole or tear with a length or diameter of approximately 1 mm*. The corner air cell was identified, and a small soldering iron tip was heated and

held on the cell until a hole was formed, with attention to potential smoke formation. Tweezers were then used to hold the hole open while it cools, and the cell is marked with a permanent marker.

Figure 4: Illustration of two-finger test method

Results and Performance

Booster's performance in these tests was noteworthy. In the *Duration to Alarm tests*, it consistently detected leaks far quicker than the one-hour benchmark, with an average detection time of approximately *7 minutes and 30 seconds (See Table 2)*. The *Leak management tests* demonstrated Booster's ability to maintain proper cushion inflation for a full hour, even with an active leak (See Table 2). This stood in sharp contrast to cushions without Booster, which bottomed out within 7 minutes under similar test conditions.

Test 1: Small Leak - Duration to Alarm				
Test Trial	**Duration to Alarm**	**Cushion Type**	**Cushion Size**	**Chair Type**
0001	7 min, 43 s	Star StabilAir	17.25″ x 17.25″ x 4″	Sling WC
0002	8 min, 58 s	Star StabilAir	17.25″ x 17.25″ x 4″	Sling WC
0003	7 min, 57 s	ROHO, Standard single cell	16.5″ x 18.5″ x 4″	Sling WC
0004	8 min, 27 s	ROHO, Standard single cell	16.5″ x 18.5″ x 4″	Sling WC
0005	10 min, 48 s	ROHO Hybrid Select*	Standard 18″ x 16″	Sling WC
0006	8 min, 22 s	ROHO Hybrid Select*	Standard 18″ x 16″	Sling WC

0007	8 min, 51s	ROHO, Standard single cell	16.5″ x 18.5″ x 4″	Power WC
0008	8 min, 10s	Star StabilAir	17.25″ x 17.25″ x 4″	Power WC
0009	2 min, 23s	Star StabilAir**	21″ x 21″ x 3″	Power WC
0010	12 min, 48s	Star StabilAir***	17.25″ x 17.25″ x 4″	Power WC
0011	1 min, 5s	Star StabilAir	17.25″ x 17.25″ x 4″	Power WC
0012	5 min, 57s	Star StabilAir	17.25″ x 17.25″ x 4″	Sling WC

*ROHO Hybrid Select cushion was tested with leak produced through use of a manual regulator.

** Cushion tested had a leak caused from an induced 1.32 mm diameter hole. Reference Figure 3.'

***Test initiated after increase cushion pressure by 50%

Table 2: *Data collected from* ***the duration to alarm test****.*

Test 2: Leak Management - Clinical Effects on Pressure Redistribution							
Test Trial	**DI at T0**	**DI at T60**	**PPI at T0**	**PPI at T60**	**Cushion Type**	**Cushion Size**	**Chair Type**
0001	34	29	50 mmHg	42 mmHg	Star StabilAir	17.25″ x 17.25″ x 4″	Sling WC
0002	34	33	55 mmHg	52 mmHg	Star StabilAir	17.25″ x 17.25″ x 4″	Power WC
0003	33	29	53 mmHg	95 mmHg	Star StabilAir	17.25″ x 17.25″ x 4″	Manual WC (Hard base)
0004	29	29	59 mmHg	95 mmHg	ROHO, Standard single cell	16.5″ x 18.5″ x 4″	Manual WC (Hard base)
0005	35	33	59 mmHg	84 mmHg	ROHO, Standard single cell	16.5″ x 18.5″ x 4″	Manual WC (Hard base)

Table 3: Data collected from the start of the test (T0) to the 1 hour mark (T 60), with a tester seated on a leaking cushion with Booster connected. *T0 = test start. T60 = 60 minutes* into the test.

Figures 5, 6, and 7 illustrate pressure map data from a single leak management test trial, comparing a cushion's performance with and without Booster connected. Data was collected at T0 (test start) and T60 (1-hour into the test), as illustrated in Figures 5 and 6, to demonstrate Booster's efficacy in maintaining cushion inflation. When connected, overall pressure changes in the cushion over the test period were minimal, showing that Booster was able to maintain pressure map DI values at T60 or below T0 values (See Figure 5 & 6). In contrast, when Booster was disconnected, pressure map data showed significant pressure spikes, potentially compromising user comfort and safety (See Table 3; Figure 7). A DI increase from 29 at T60 to 39 was observed, along with a visual confirmation on the pressure map that the user's left IT had bottomed-out during the *leak without Booster test, showing a maximum pressure of 200mmHg (See Figure 7)*. Note that tester posture was not controlled for, meaning PPI tended to vary over the course of the 1 hour test.

These pressure map recordings demonstrate Booster's ability to mitigate and reduce the rate at which bottoming out occurs. With Booster managing the leak, the average Peak Pressure Index (PPI) increased by approximately 18.4 mmHg (See Table 3). In Trial 1, the PPI actually decreased from 50 to 42 at T60, compared to an 86 mmHg increase from the original PPI at T0 when Booster was disconnected (See Figures 5,6 & 7). Furthermore, without Booster, the cushion was shown to have bottomed out the user within 7 minutes due to the leak.

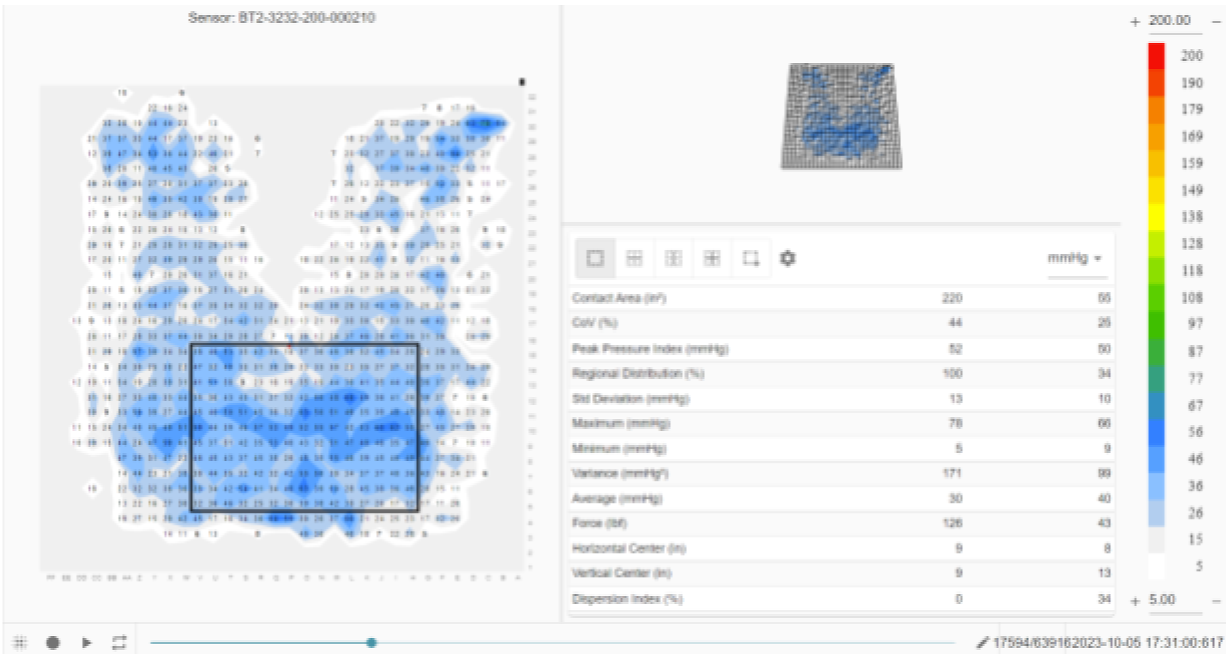

Figure 5: Pressure map data of Trial 1 at T0

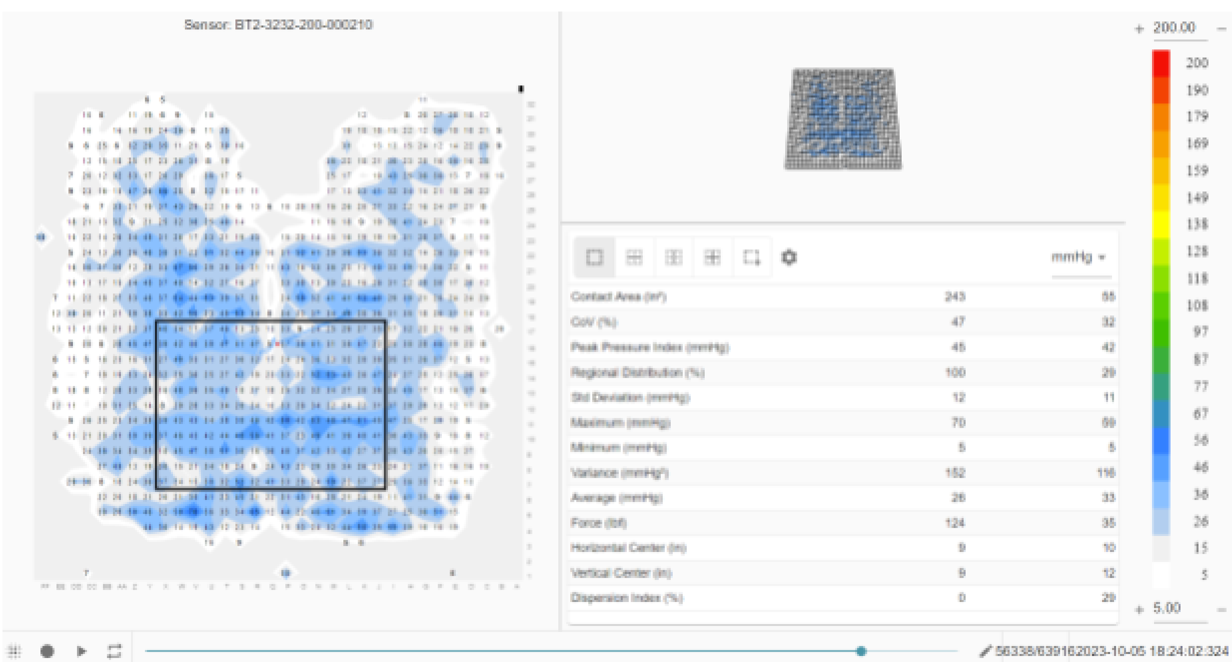

Figure 6: Pressure map data of Trial 1 at T60 when Booster is connected

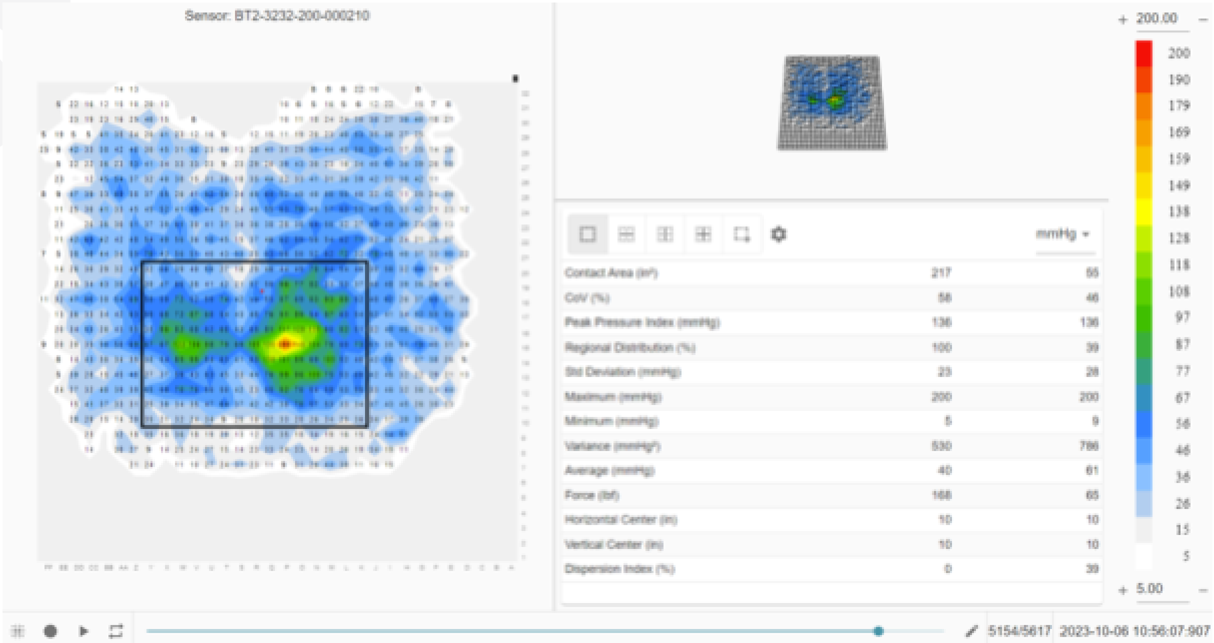

Figure 7: Pressure map data from Trial 1's cushion after Booster was disconnected. This was done to evaluate what would happen if a wheelchair user stopped using the device on their damaged cushion. Cushion bottomed out after 7 minutes

Conclusion

The results found through the small leak testing offered strong evidence of Booster's capability to effectively detect and manage small leaks in air cushions. Its rapid detection and sustained pressure management suggest that Booster is a valuable tool in preventing the negative consequences of undetected cushion damage. By maintaining proper cushion inflation in the presence of small leaks, Booster demonstrated its ability to enhance user comfort and reduce the risk of pressure injuries, marking a significant advancement in cushion technology.

2. Large Leak Tests

Methodology

The large leak tests were designed to evaluate Booster's ability to detect and respond to significant air loss in cushions. A large leak was defined as air loss through a hole approximately 3 mm in diameter. This damage was simulated by attaching a manually adjustable relief valve to the cushion's fill port, allowing for controlled creation of a large leak. The test cushions were properly positioned on a wheelchair with the cushion's relief valve oriented as per manufacturer instructions. With a tester seated, the large leak was initiated by opening the attached relief valve, and a timer was started to record Booster leak detection response time.

Results and Performance

Booster's performance in these tests again exceeded expectations. The device consistently detected large leaks well within the specified 10-minute timeframe (See Table 3). On average, Booster took just 1 minute and 49 seconds to detect a large leak and trigger a warning. Through 20 trial runs, the device successfully alerted the user within the required time limit. Notably, in 12 out of 20 trials, Booster displayed exceptional responsiveness by detecting the leak and sounding an alert in less than one minute. As part of its design, Booster was developed to provide both auditory and visual cues when detecting a leak. The tests confirmed that the device successfully provided these alerts, ensuring that users of the device would be promptly notified of any significant air loss in their cushions.

Test 3: Large Leak Test - Duration to Alarm				
Test Trial	**Duration to Alarm**	**Cushion Type**	**Cushion Size**	**Chair Type**
0001	0 min, 34 s	ROHO, Standard single cell	18.25″ x 18.25″ x 4″	Power WC
0002*	0 min, 50 s	ROHO, Standard single cell	18.25″ x 18.25″ x 4″	Power WC
0003	0 min, 35 s	ROHO, Standard single cell	18.25″ x 18.25″ x 4″	Power WC
0004	0 min, 48 s	ROHO, Standard single cell	18.25″ x 18.25″ x 4″	Sling WC
0005	0 min, 47 s	ROHO, Standard single cell	18.25″ x 18.25″ x 4″	Sling WC
0006	0 min, 48 s	ROHO, Standard single cell	18.25″ x 18.25″ x 4″	Sling WC
0007	3 min, 55 s	ROHO, Hybrid single cell	Standard 18″ x 16″	Power WC
0008	3 min, 46 s	ROHO, Hybrid single cell	Standard 18″ x 16″	Power WC
0009	1 min, 09 s	ROHO, Hybrid single cell	Standard 18″ x 16″	Power WC
0010	5 min, 10 s	ROHO, Hybrid single cell	Standard 18″ x 16″	Power WC
0011	4 min, 47 s	ROHO, Hybrid single cell	Standard 18″ x 16″	Sling WC

0012	3 min, 01 s	ROHO, Hybrid single cell	Standard 18″ x 16″	Sling WC
0013	5 min, 14 s	ROHO, Hybrid single cell	Standard 18″ x 16″	Sling WC
0014	0 min, 32 s	Star, Standard	17.25″ x 17.25″ x 4″	Sling WC
0015	2 min, 42 s	Star, Standard	17.25″ x 17.25″ x 4″	Sling WC
0016	0 min, 33 s	Star, Standard	17.25″ x 17.25″ x 4″	Sling WC
0017	0 min, 50 s	Star, Standard	17.25″ x 17.25″ x 4″	Power WC
0018	0 min, 40 s	Star, Standard	17.25″ x 17.25″ x 4″	Power WC
0019	0 min, 34 s	Star, Standard	17.25″ x 17.25″ x 4″	Sling WC
0020	0 min, 43 s	Star, Standard	17.25″ x 17.25″ x 4″	Sling WC

*Tested at 25% inflation

Table 4: *Data collected from large leak testing*

Conclusion

The large leak tests demonstrated Booster's remarkable efficiency in detecting substantial air loss in test cushions. By consistently alerting users to large leaks in under two minutes on average, Booster far exceeded the 10-minute detection requirement. This swift response time is crucial for preventing extended periods of inadequate cushion inflation and bottoming out, which could lead to discomfort or potential injury. While Booster is not designed to maintain cushion pressure in the presence of such large leaks, its rapid detection and alert system provide users with the timely information needed to address the issue promptly. These results suggest that Booster can significantly enhance the safety and reliability of air-cell cushions, offering users greater peace of mind and potentially reducing the risk of complications associated with sudden, substantial air loss.

3. *Weight Change Management Tests*

Methodology

The weight change management tests were designed to assess Booster's ability to maintain appropriate cushion inflation levels under varying applied weights. Using an intact cushion, initial pressure mapping results were taken with the tester seated for 5 minutes, recording Distribution Index (DI), Peak Pressure Index (PPI), and pressure map images. The tester then held incrementally heavier weights: 10 lbs, then 25 lbs, and finally 50 lbs total. At each stage DI, PPI, pressure mapping images and notes indicating any audible indications of pumping or venting from the device were collected. This test simulated scenarios such as a user placing a heavy backpack on their thighs or a user experiencing weight gain while using Booster.

Peak Pressure Index as Weight Increases				
Trial	**0 LBS**	**10 LBS**	**25 LBS**	**50 LBS**
1	53	49	53	53
2	75	68	67	75
3	69	49	52	65
4	79	66	69	66
5	65	72	73	80
6 (Control - no unit)	55	74	85	91

Table 5*: Weight Management data collected as applied weight increases. Data was collected while from a tester using a Star Standard Air on a rigid manual chair*

Results and Performance

In four out of five trials, the Peak Pressure Index (PPI) did not increase despite the addition of up to 50 lbs of weight, indicating successful air pressure adjustments. One trial showed a PPI increase of 15 after adding 50 lbs, which was noted as a potential outlier requiring further investigation

A control trial without Booster connected was conducted to assess the device's overall impact. The results clearly demonstrated Booster's effectiveness, with the average PPI of the experimental trials showing a significant reduction compared to the control. This highlights Booster's ability to manage pressure effectively when user weight increases.

Conclusion

The Weight Change Management tests affirmed Booster's capability to adjust cushion air pressure in response to weight increases. The device maintained stable PPI values in the majority of trials, successfully keeping these metrics within 10% of baseline values in most cases (See Figure 8 and 9). This performance suggests that Booster can effectively maintain the cushion's pressure setpoint as determined by a user or clinician, even under changing load conditions.

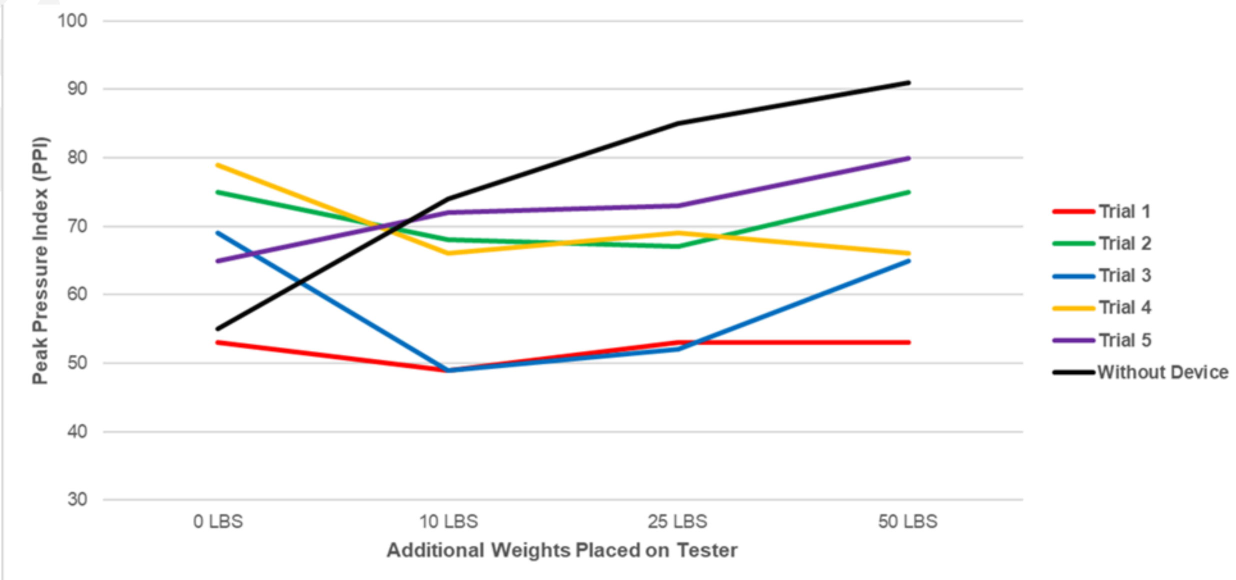

Figure 8: Effect of Kalogon AMS on Interface Pressure as User Weight Increases

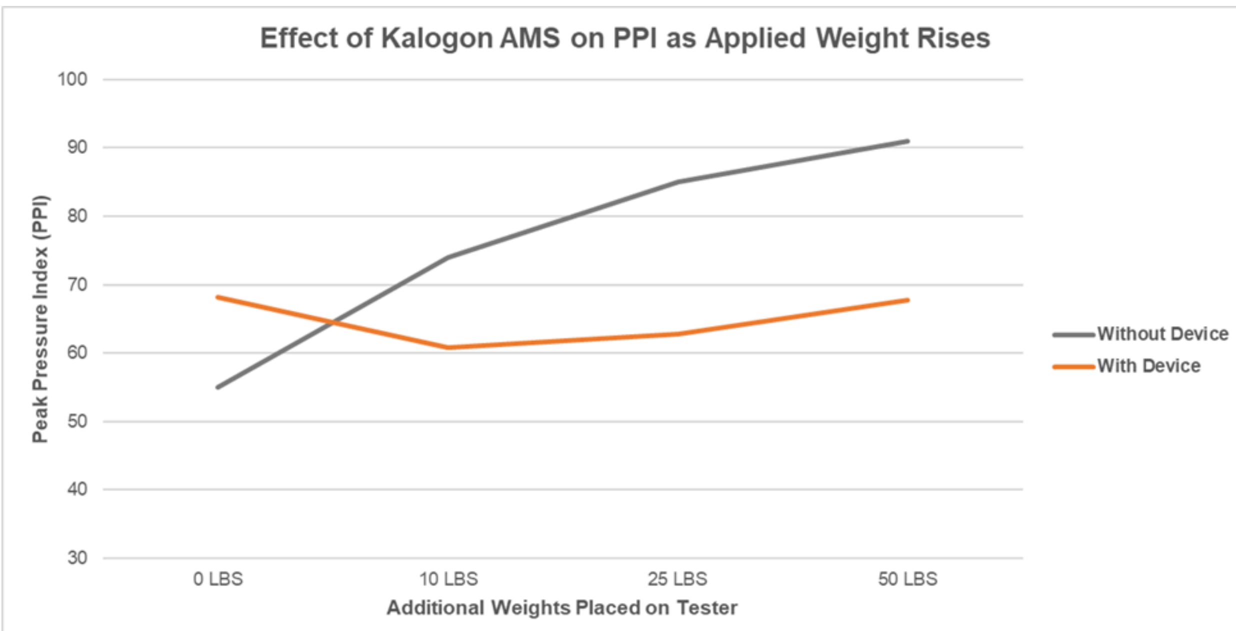

Figure 9: Average PPI Change with and without the device during weight management

These results indicate that Booster can provide significant benefits for users whose weight may fluctuate due to various factors. By maintaining consistent pressure distribution despite weight variations, Booster demonstrates potential for enhancing user comfort and potentially reducing the risk of pressure-related issues in dynamic real-world conditions.

Conclusion

Pressure injuries remain a significant issue today, with high prevalence and substantial costs. Research suggests that a majority of these injuries are preventable, and prevention is more cost-effective than treatment (Ginningberg et al., 2018). Air-based cushions, along alternating air pressure cushions, offer effective options for reducing and preventing pressure injury risks. As such, Booster is a valuable technology that enhances the efficiency of single-chamber vertical air cell wheelchair cushions. Booster ensures proper inflation maintenance, provides leak detection and management, and offers a user-friendly way of adjusting inflation levels. Kalogon continues to work on enhancing the seating experience of people who spend most of their time sitting. Championed by its mission *To help everyone live an active, seated life,* Kalogon works to advance technology in this space to reduce the health risks and costs associated with pressure injuries.

Additional links

For information on device Instructions and User manual (click here)

To read more about Booster on our website (click here)

References

Agency for Healthcare Research and Quality. (2014, October). Are we ready for this change?. https://www.ahrq.gov/patient-safety/settings/hospital/resource/pressureulcer/tool/pu1.html

Bharucha, J. B., Seaman, L., Powers, M., Kelly, E., Seaman, R., Forcier, L., McGinnis, J., Nodiff, I., Pawlak, B., Snyder, S., Nodiff, S., Patel, R., Squitieri, R., & Wang, L. (2018). A Prospective Randomized Clinical Trial of a Novel, Noninvasive Perfusion Enhancement System for the Prevention of Hospital-Acquired Sacral Pressure Injuries. *Journal of wound, ostomy, and continence nursing : official publication of The Wound, Ostomy and Continence Nurses Society*, *45*(4), 310–318. https://doi.org/10.1097/WON.0000000000000450

Cook, A. M., Polgar, J. M., & Encarnação, P. (2019). *Assistive Technologies-E-Book: Assistive Technologies-E-Book*. Elsevier Health Sciences.

Graves, N., Birrell, F., & Whitby, M. (2005). Effect of Pressure Ulcers on Length of Hospital Stay. *Infection Control & Hospital Epidemiology*, *26*(3), 293–297. https://doi.org/10.1086/502542

Gefen A (2018) The future of pressure ulcer prevention is here: detecting and targeting inflammation early. EWMA J 19:7–13

Gefen, A., Brienza, D. M., Cuddigan, J., Haesler, E., & Kottner, J. (2022). Our contemporary understanding of the aetiology of pressure ulcers/pressure injuries. *International wound journal*, *19*(3), 692–704. https://doi.org/10.1111/iwj.13667

Gunningberg L, Sving E, Hommel A, Ålenius C, Wiger P, Bååth C. Tracking pressure injuries as adverse events: National use of the Global Trigger Tool over a 4-year period. *J Eval Clin Pract*. 2019; 25: 21–27. https://doi.org/10.1111/jep.12996

Levy, A., Shoham, N., Kopplin, K., & Gefen, A. (2018). The critical characteristics of a good wheelchair cushion. In M. Romanelli, M. Clark, A. Gefen, & G. Ciprandi (Eds.), *Science and practice of pressure ulcer management* (2nd ed., pp. 17–31). London, England: Springer-Verlag. ISBN: 978-1-4471-7411-0 .

Lustig, A., Margi, R., Orlov, A., Orlova, D., Azaria, L., & Gefen, A. (2021). The mechanobiology theory of the development of medical device-related pressure ulcers revealed through a cell-scale computational modeling framework. *Biomechanics and Modeling in Mechanobiology,* 20(3), 851–860.

Mondragon N, Zito PM. Pressure Injury. [Updated 2024 Feb 28]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK557868/

Moore, Z., Avsar, P., Conaty, L., Moore, D. H., Patton, D., & O'Connor, T. (2019). The prevalence of pressure ulcers in Europe, what does the European data tell us: a systematic review. *Journal of wound care*, *28*(11), 710–719. https://doi.org/10.12968/jowc.2019.28.11.710

New Mobility. (n.d.). Five Pro Tips for Flying with a Power Wheelchair. Retrieved June 28, 2024, from https://newmobility.com/five-pro-tips-for-flying-with-a-power-wheelchair/

Park, M. O., & Lee, S. H. (2019). Effects of seating education and cushion management for adaptive sitting posture in spinal cord injury: Two case reports. *Medicine*, *98*(4), e14231. https://doi.org/10.1097/MD.0000000000014231

Padula, W. V., Mishra, M. K., Makic, M. B. F., & Sullivan, P. W. (2011). Improving the Quality of Pressure Ulcer Care With Prevention: A Cost-Effectiveness Analysis. *Medical Care*, *49*(4), 385–392. http://www.jstor.org/stable/41103930

Song, Y. P., Shen, H. W., Cai, J. Y., Zha, M. L., & Chen, H. L. (2019). The relationship between pressure injury complication and mortality risk of older patients in follow-up: A systematic review and meta-analysis. *International wound journal*, *16*(6), 1533–1544. https://doi.org/10.1111/iwj.13243

Stephens, M., & Bartley, C. A. (2018). Understanding the association between pressure ulcers and sitting in adults what does it mean for me and my carers? Seating guidelines for people, carers and health & social care professionals. *Journal of tissue viability*, *27*(1), 59–73. https://doi.org/10.1016/j.jtv.2017.09.004

U.S. Food and Drug Administration. (n.d.). MAUDE - Manufacturer and User Facility Device Experience. Retrieved June 28, 2024, from https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/results.cfm

Qian, L., Yan, S., Ting, S. T., Han, Z. M., & Qi, T. (2024). Complications and psychological impact of pressure ulcers on patients and caregivers. *International wound journal*, *21*(4), e14836. https://doi.org/10.1111/iwj.14836

Vanderwee, K., Grypdonck, M., & Defloor, T. (2008). Alternating pressure air mattresses as prevention for pressure ulcers: a literature review. *International journal of nursing studies*, *45*(5), 784–801. https://doi.org/10.1016/j.ijnurstu.2007.07.003

Vanderwee, K., Clark, M., Dealey, C., Gunningberg, L., & Defloor, T. (2007). Pressure ulcer prevalence in Europe: a pilot study. *Journal of evaluation in clinical practice*, *13*(2), 227–235. https://doi.org/10.1111/j.1365-2753.2006.00684.x

Vecin NM, Gater DR. Pressure Injuries and Management after Spinal Cord Injury. *Journal of Personalized Medicine*. 2022; 12(7):1130. https://doi.org/10.3390/jpm12071130