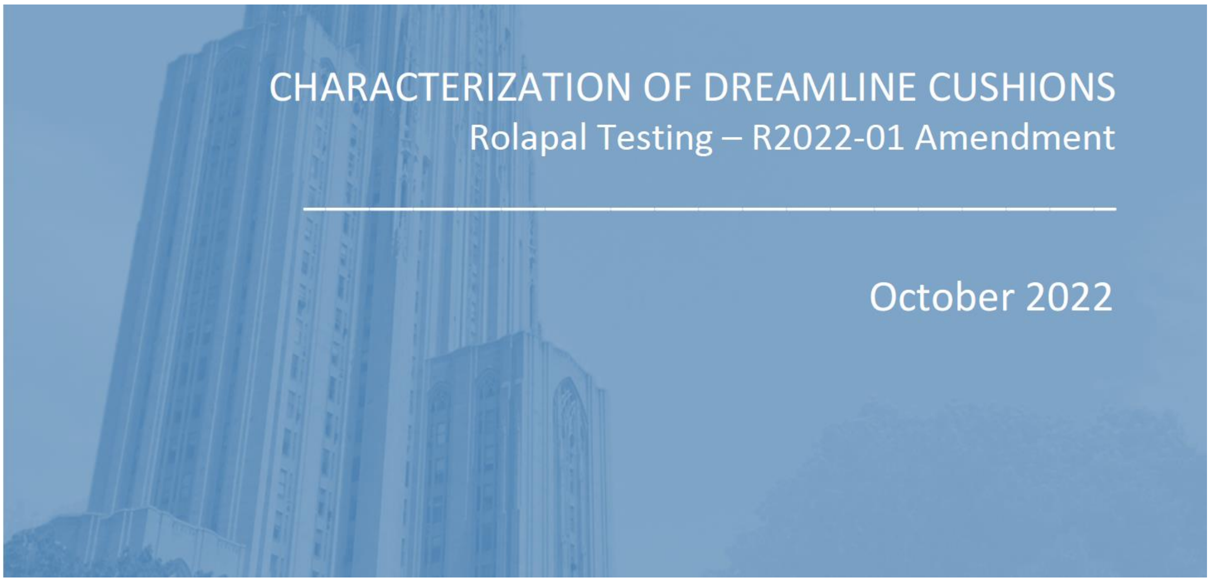
Dreamline

WHEELCHAIR SEATING

INDEPENDENT CHARACTERIZATION TESTING BY UNIVERSITY



ROLAPAL

OVERVIEW

Background

Seat cushions provide a critical interface between the wheelchair and user and have an impact
on positioning and tissue integrity. Published technical standards for wheelchair seat cushions
provide standardized terminology and methods for characterizing product performance. Ten
ISO 16840 seating standards have been published (https://www.iso.org/committee/53792/x/catalogue/). These voluntary standards provide information that can be used by manufacturers to assess and benchmark their products, by consumers and clinicians to compare and select products, and by regulators, purchasers and third-party payers in regulatory and purchasing policies.

Methodology

ISO Standards

The following ISO standards should be referenced for more information on the procedures described in this test report:

- **ISO 16840-2:** *Determination of physical and mechanical characteristics of seat cushions intended to manage tissue integrity*
- **ISO 16840-6:** *Simulated use and determination of the changes in properties of seat cushions*
- ***ISO 16840-12****: Apparatus and method for cushion envelopment testing*
- ***ISO 16840-13****: Determination of the lateral stability property of a seat cushion*

Procedural overview

The cushions underwent the following characterization tests:

- ***Loaded Contour Depth and Overload Deflection (ISO 16840-2:2018 Clause 11),*** *a test to evaluate a cushion's ability to immerse the buttocks;*
- ***Horizontal Stiffness (ISO 16840-2:2018 Annex C),*** *a test to evaluate the cushion's response to slight horizontal movements in the forward direction.*
- ***Lateral Stability (ISO 16840-13:2021),*** *a test to evaluate a cushion's ability to resist moments at the pelvis;*
- ***Pressure Mapping (ISO 16840-6:2015 Clause 14),*** *a test that utilizes interface pressure measurements to assess the magnitude and distribution of pressure on a loaded cushion before and after aging (relative changes).*
- ***Envelopment (ISO 16840-12:2021),*** *a test that characterizes a cushion's ability to envelop and immerse the buttocks;*

Cushion Selection

The samples listed in Tables 1 were provided for testing.

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The samples listed in Tables 1 were provided for testing.

Table 1. Samples provided for all tests

Model

1 Woven Air (16” x 16”)*

2 G7 with Air Insert (16” x 16”)**

3 G7 with Gel Insert (16” x 16”)

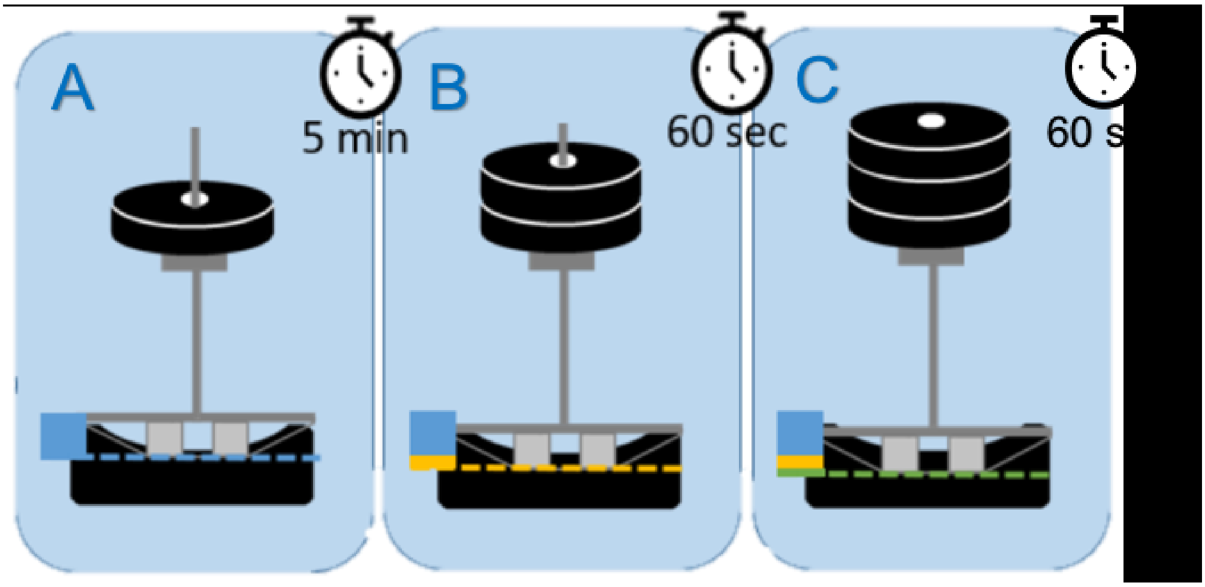
*height adjusted by adding additional air packets as needed per manufacturer instructions

*****For the R2022-01 Amendment Report, a 6-cell configuration of the G7 with Air was added to Pressure Mapping test results and used in the newly added Envelopment test results for all 3 cushions. This 6-cell configuration is the G7 Air with one left & right air tube removed from the ischial well.***

Loaded Contour Depth and Overload Deflection

Test Overview and Methodology

Loaded contour depth and overload deflection is a test that measures the ability of a cushion to immerse the buttocks. Immersion is defined as the depth to which a person sinks into the cushion. A higher Loaded Contour Depth may indicate more immersion into the cushion and greater distribution of pressure on the soft tissue. Cushions with higher additional immersion under the overload conditions have higher margins of safety against bottoming out. Figure 1 shows a visualization of the Loaded Contour Depth procedures from ISO 16840-2:2018, Clause 11 that were followed.



There are three key outcomes of this test: Loaded Contour Depth, Overload Deflection 1 and Overload Deflection 2. Loaded Contour Depth is the depth of immersion of the basepoints (ITs) of a cushion loading indenter (includes pre-contouring and loaded contouring). Overload Deflection 1 is the additional immersion beyond the Loaded contour depth with a 33% increase in load from the nominal load. Overload Deflection 2 is the additional immersion beyond the Loaded contour depth with a 66% increase in load from the nominal load.

Results

ISO Loaded Contour Depth test results with the ISO 16840-2 40-mm cushion loading indenter can be seen in Table 2 and Figures 2-5.

Table 2. LCD and ODs using ISO test method and 40-mm cushion loading indenter

	Loaded Contour Depth (mm)	Overload Deflection 1 (mm)	Overload Deflection 2 (mm)
Woven Air	51	4.9	8.7
G7 Air (8-cell)	56	4.1	8.2
G7 Gel	59	3.2	6.1

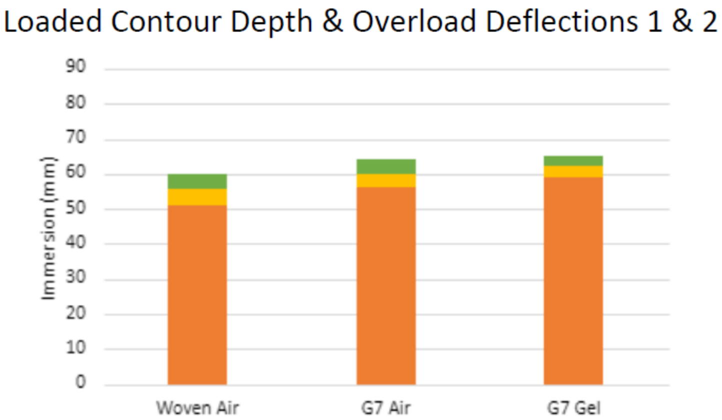


Figure 2. Loaded Contour Depth (orange), Overload Deflection 1 (yellow) and Overload Deflection 2 (yellow + green).

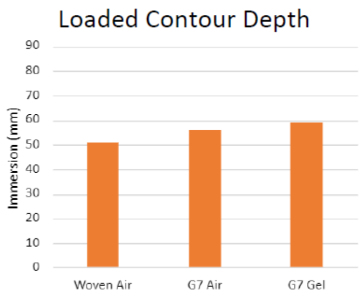


Figure 3. Loaded Contour Depth (orange)

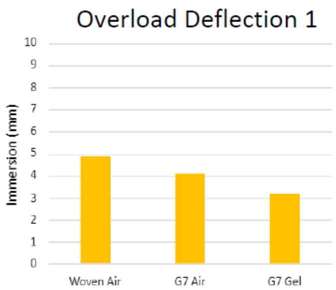


Figure 4. Overload Deflection 1 (yellow)

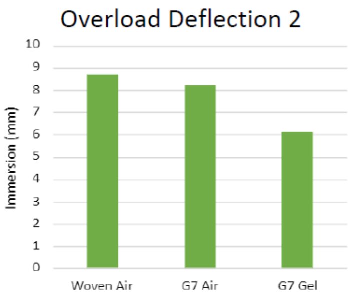


Figure 5. Overload Deflection 2 (green)

Observations and Conclusions

• All three Rolapal cushions exhibited similar loaded contour depth immersions (Table 2 and Figures 2-3).

• The G7 cushion with the gel insert exhibited lower overload immersions than the other two cushions (Table 2 and Figures 4-5).

Rehabilitation Engineering Research Center (RERC) 50 cushion cohort.

○ Relative to the cohort, loaded contour depth results for all three Rolapal cushions fell in the mid-to-high range.

Pressure Mapping

Test Overview and Methodology

Pressure Mapping is a test that utilizes interface pressure measurements to assess the magnitude and distribution of pressure on a loaded cushion. Figure 6a shows a visualization of the Pressure Mapping test procedures from ISO 16840-6:2015 Clause 14 that were followed. This method is not a validated or standardized test method and is intended to be used to compare pressure mapping metrics before and after simulated aging.

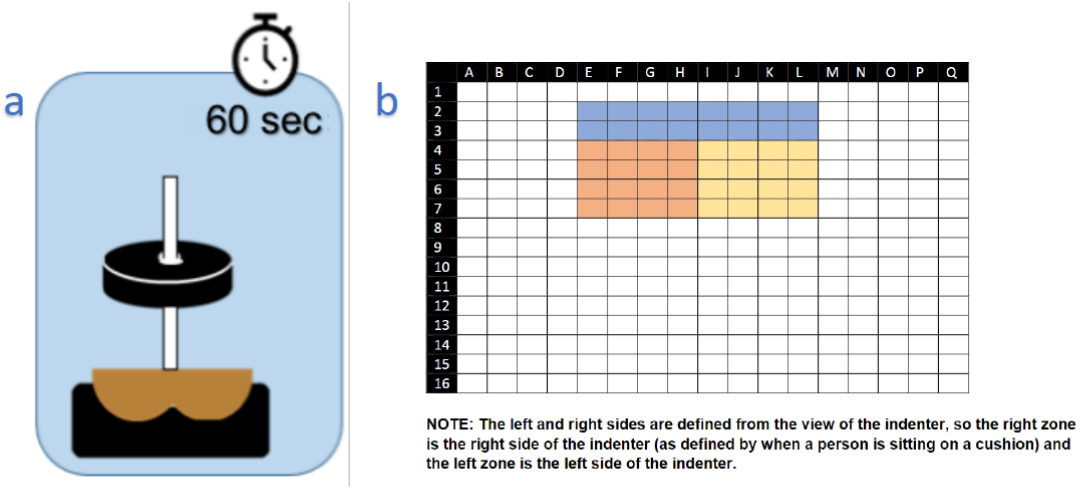


Figure 6. a: The cushion is loaded with a rigid cushion loading indenter and load totalling 500N and pressure map placed at the interface between the cushion and indenter records for 60 seconds. b: Guidance on interpretation of the pressure map and base zones. Representation of a pressure map that shows Right (orange) and Left (yellow) Base Zones as well as Center (blue) zone (a 16x16 map is shown, but a 32x32 array was used for testing).

The standard defines several key outcomes for the interface pressure measurement test related the base zones highlighted in Figure 6b including: Peak Pressure Index for the right and left base zones; Total force; Percent total force for the right, left and center base zones; Dispersion index; and Contact area. For more information on these metrics please reference ISO 16840-6:2015 Clause 14. A BT2-3232-200 BodiTrak2 pressure mat that has a 32x32 array and 47cm x 47cm sensing area was used for pressure mapping pressure measurements. Each sensor is 11mm x 11mm with 2mm spacing and saturates at 200 mmHg.

Results

Pressure Mapping test results can be seen in Table 3 and Figures 7-12. Additional figures can be found in Appendix A.

Table 3. Pressure Mapping Results averaged over five trials

Table 3. Pressure Mapping Results averaged over five trials

	Dispersion Index (%)	PPI – Left Base Zone (mmHg)	PPI – Right Base Zone (mmHg)	Contact Area (mm²)
Woven Air	62	97	106	70527
G7 Air	54	105	109	63305
G7 Air (6 Cell)	49	90	89	73398
G7 Gel	42	135	130	72723

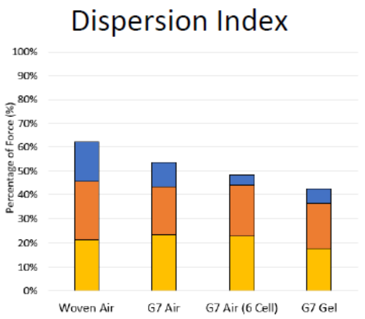


Figure 7. Percentage of force seen on the Left Base Zone (LBZ) (yellow), Right Base Zone (RBZ) (orange) and Rear center zone (CZ) (blue).

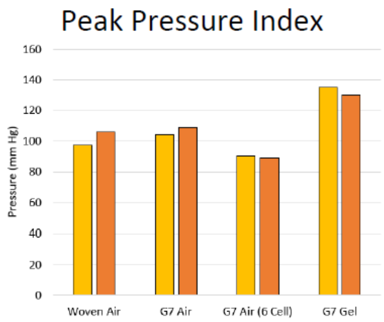


Figure 8. Peak pressure index of the Left Base Zone (LBZ) (yellow) and Right Base Zone (RBZ) (orange).

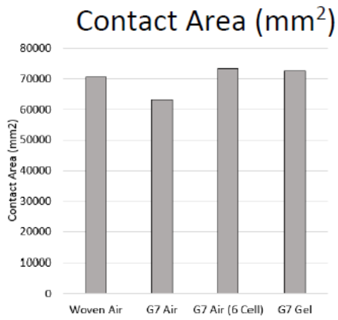


Figure 9. Contact Area (gray)

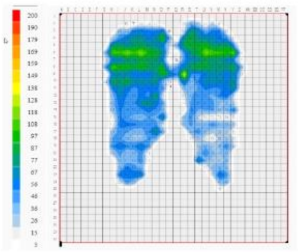


Figure 10. Sample Pressure Mapping output for the Woven Air 60 seconds after load application

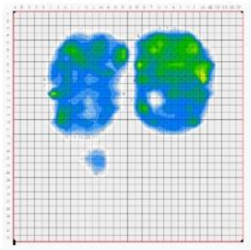


Figure 11. Sample Pressure Mapping output for the G7 Air 60 seconds after load application

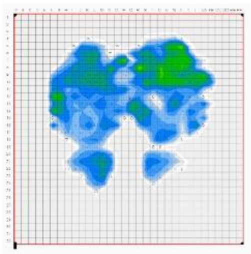


Figure 12. Sample Pressure Mapping output for the G7 Air (6 cell) 60 seconds after load application

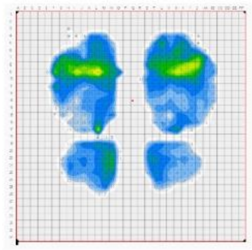


Figure 13. Sample Pressure Mapping output for the G7 Gel 60 seconds after load application

Observations and Conclusions

- ***The G7 Air (6 cell) cushion (i.e., removal of one air tube from both the left and right side in the ischial well) exhibited the largest contact area and lowest Peak Pressure Indices of the Dreamline cushions tested in the R2022-01 cohort.***
- The original G7 cushion with the air insert (8 cell) exhibited the lowest contact area (Table 3 and Figure 9).
- The G7 cushion with the gel insert exhibited higher peak pressure indices but lower dispersion index due to lack of loading in the gluteal cleft than the other cushions (Table 3 and Figure 7-8).
- The pressure map visualization shows that there is minimal to no distribution of load to the thighs for the original G7 cushion with the air insert (Figure 11). This was improved with removal of air tubes in the G7 Air 6-cell configuration (Figure 12).

  - Relative to the 50 cushion cohort, Rolapal cushions exhibited contact areas and PPI in the mid-to-high range.

Lateral Stability

Test Overview and Methodology

The Lateral Stability test evaluates the cushion's ability to resist moments at the pelvis. Moments in the test method are created with an off-centre load applied to a standard indenter simulating the buttocks and upper thighs. Resulting indenter tilt angles are measured to characterize the cushion response. The intended use of the method is to differentiate stability performance between cushion models and evaluate the effect of setup configurations and the addition of postural inserts on individual cushions. Figure 14 shows a visualization of the Lateral Stability test procedures in the ISO 16840-13 standard that were followed.

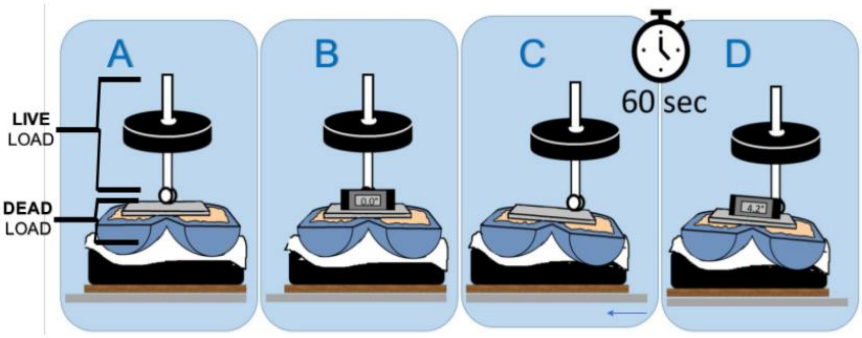


Figure 14. A: The cushion is loaded with a live load (the (60%) portion of the load that translates in the horizontal plane to shift the center of mass relative to the test cushion) and dead load (the (40%) portion of the total load, including the rigid cushion loading indenter, that does not translate in the horizontal plane relative to the test cushion) totaling 500N; B: The indenter is leveled and the initial angle is recorded; C: The dead load is shifted 75 mm laterally to create a tilt condition; D: The tilt angle is recorded every 10 seconds for 60 seconds after the shift is applied.

The main outcome of this test is the change in tilt angle, which indicates the amount of rotation of the indenter allowed by the cushion. Changes in lateral tilt are averaged over five trials and measured every 10 seconds for 60 seconds after a 75 mm lateral weight shift is applied. Anterior-posterior tilt was measured at 0 and 60 seconds (this is a deviation from ISO 16840-13).

Investigating interface pressure can supplement the tilt angle data. Procedures for the pressure mapping portion of the lateral stability test can be found in Annex A of ISO 16840-13. A BT2-3232-200 BodiTrak2 pressure mat that has a 32x32 array and 47cm x 47cm sensing area was used for pressure mapping pressure measurements. Each sensor is 11mm x 11mm with 2mm spacing and saturates at 200 mmHg.

Results

Lateral Stability test results can be seen in Table 4 and Figure 15. Figure 16-18 shows the nature of the cushion's support during a lateral tilt event via distribution of pressure at 60s.

Table 4. Average lateral tilt (degrees) of five trials at each time point

	Lateral tilt (°) at					
	10s	20s	30s	40s	50s	60s
Woven Air	3.2	3.2	3.3	3.3	3.3	3.3
G7 Air (8 cell)	2.8	2.9	3	3.1	3.1	3.2
G7 Gel	3	3.2	3.3	3.4	3.4	3.5

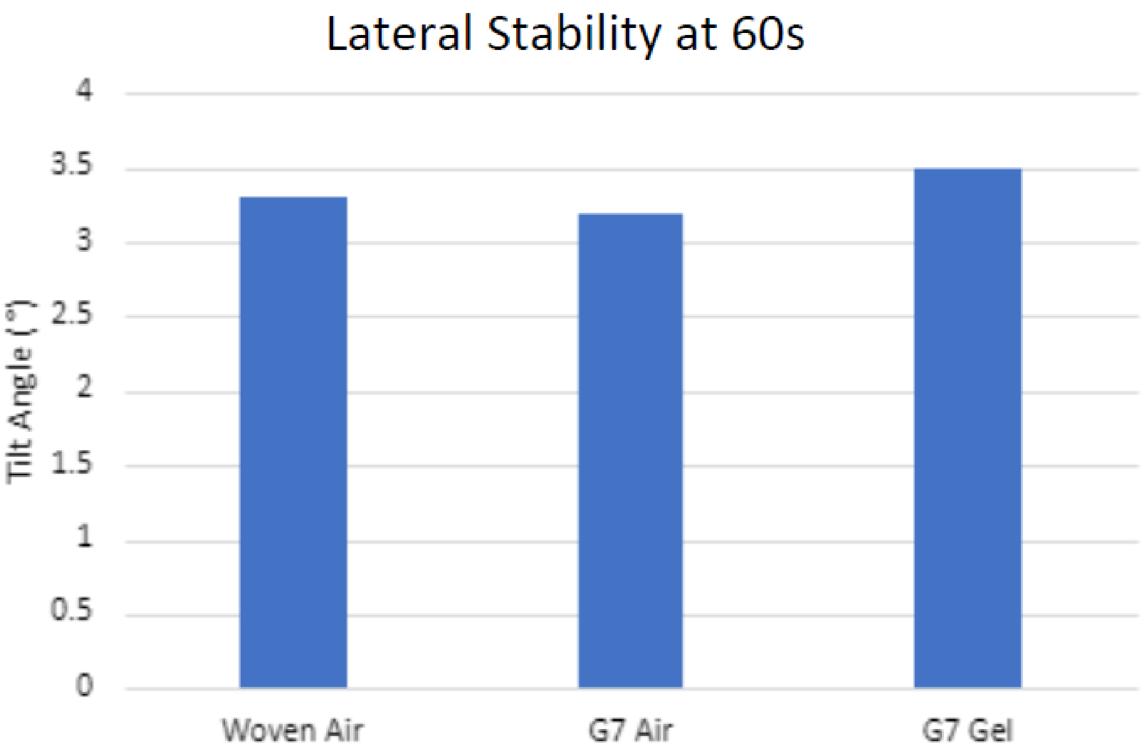


Figure 15..Average tilt angle at 60s.

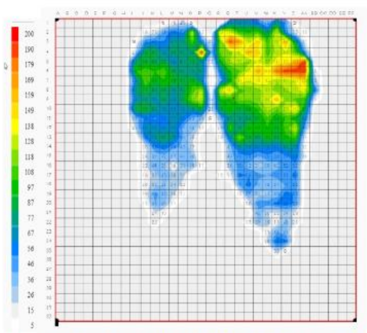


Figure 16. Lateral Stability test pressure map for the Woven Air 60 seconds after weight shift application

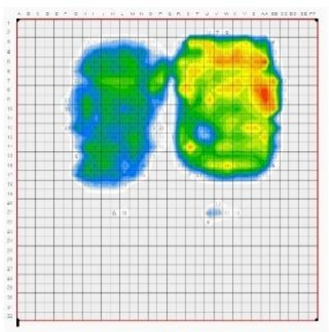


Figure 17. Lateral Stability test pressure map for the G7 Air 60 seconds after weight shift application

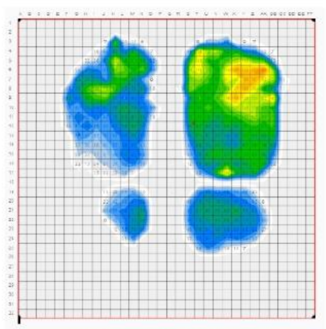


Figure 18. Lateral Stability test pressure map for the G7 Gel 60 seconds after weight shift application

Observations and Conclusions

- The Woven Air degree of tilt remained more constant over the 60 second period than the G7 cushion with the air (8 cell) and gel inserts (Table 4).
- Relative to the cohort of 50 cushions, all three Rolapal cushions exhibit low tilt reflecting a characteristically stable cushion

Horizontal Stiffness

Test Overview and Methodology

Horizontal Stiffness is a test that characterizes a cushion's response to slight horizontal movements in the forward direction, indicating resistance to pelvic movement. Figure 19 shows a visualization of the Horizontal Stiffness test procedures from ISO 16840-2:2018 Annex C that were followed.

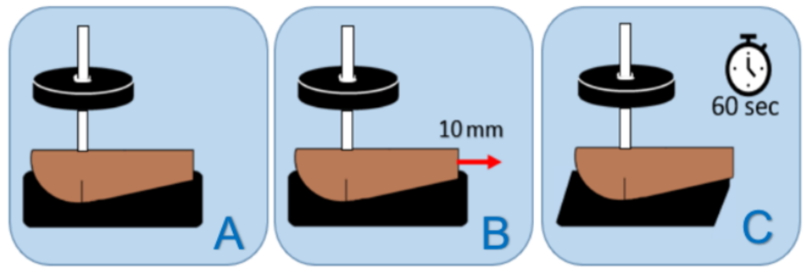


Figure 19. A: The cushion is loaded with a rigid cushion loading indenter to 500N; B: The loaded indenter is pulled 10 mm in the forward direction and the Peak Force (N) to pull the indenter is measured; C: The position is held and after 60 seconds the pull force (N) is again recorded.

Two key outcomes of this test as defined in ISO 16840-2:2018 Annex C are Peak Force (N) and Force at 60 seconds (N). The Peak Force is the maximum horizontal force required to displace a loaded cushion indenter forward 10 mm. The Force at 60 seconds is the final force measured after the 60 second hold time after displacement.

In addition to the procedures and outcomes outlines in ISO 16840-2:2018 Annex C, we attached sensor that measures shear and pressure on one basepoint (simulating the ischial tuberosity) and one thigh at the interface between the indenter and the cushion to obtain: Initial and Final Shear Force (N) and Initial and Final Interface Pressure (mmHg) for the IT and Thigh. Measurements of these interface metrics are not part of ISO 16840-2:2018 Annex C and are being provided as supplemental outcomes.

Results

Horizontal Stiffness test results can be seen in Table 5 and Figures 20-22.

Table 5. Peak Horizontal Force (N), Horizontal Force at 60 seconds (N), Shear Force at 60 seconds averaged over three trials with a 10 mm pull.

	Peak Horizontal Force (N)	Horizontal Force at 60 seconds (N)	Shear Force at 60 seconds (N)
Woven Air	114	74	29.5
G7 Air (8 cell)	123	84	23.2
G7 Gel	117	87	22.3

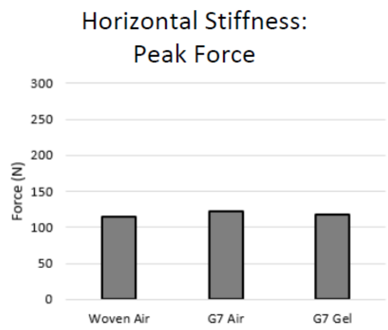


Figure 20. Peak Horizontal Force for Horizontal Stiffness with a 10mm Pull (gray)

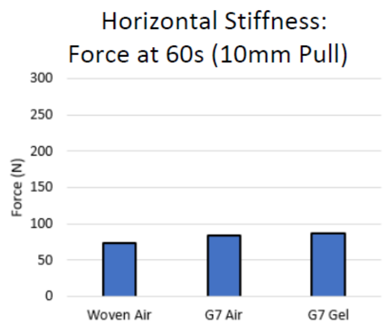


Figure 21. Horizontal Force at 60s for Horizontal Stiffness with a 10mm Pull (blue)

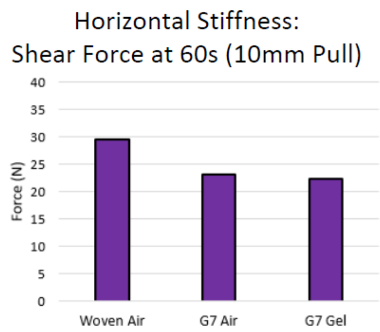


Figure 22. Shear Force at 60s for Horizontal Stiffness with a 10mm Pull (purple)

Observations and Conclusions

• The Woven air cushion exhibited a higher shear force at 60s than the G7 cushions with the air (8 cell) and gel inserts.

○ Relative to the 50 cushion cohort, all of the Rolapal cushions' peak forces and force at 60s fall on the lower end of the range.

A higher Peak or Final Force, meaning a higher "Horizontal Stiffness" outcome, may offer more stability as individuals make slight shifts on the cushion. However, there is an increased chance of tissue deformation due to shear forces between the seat cushion and buttocks, therefore a noteworthy combination is high horizontal stiffness values and low shear force.

Envelopment

Test Overview and Methodology

Envelopment is a test that measures the ability of a cushion to immerse and envelop the buttocks. A cushion's envelopment is defined as the cushion's ability to conform to the contour of the body. Envelopment measurements are captured using a combination of immersion and pressure measurements. Figure 23 shows a visualization of the Envelopment procedures from ISO 16840-12:2021 that were followed.

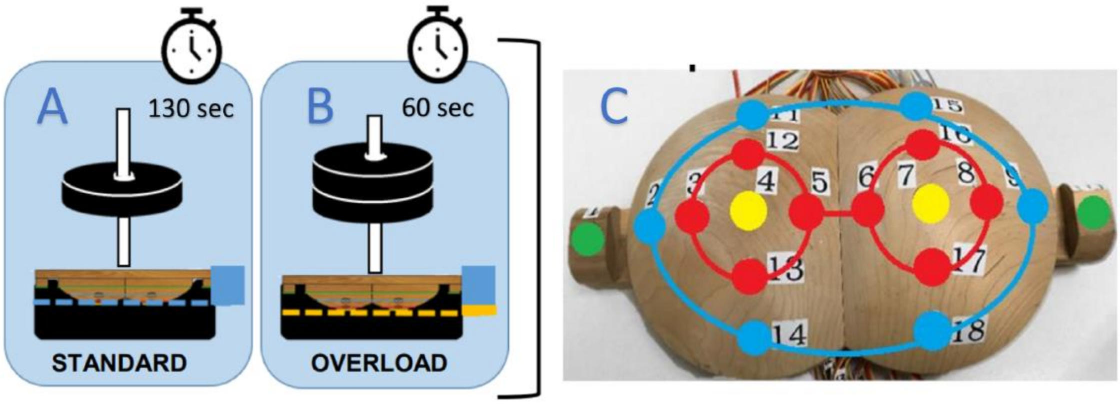


Figure 23. A: A normal load of 425N is applied to the cushion for 130 seconds then normal load immersion (mm) and normal load pressures (mmHg) at elevations 1 (yellow), 2 (red), 3 (blue), and 4 (green) are measured; B: An overload 100N greater than the normal load is applied to the cushion for 60 seconds then then overload load immersion (mm) and overload load pressures (mmHg) at elevations 1 (yellow), 2 (red), 3 (blue), and 4 (green) are measured.

There are 10 key outcomes of this test: Immersion at Normal and Overload Loads (mm) and Pressures at Elevations 1, 2, 3 and 4 at Normal and Overload loads. The Normal load Immersion is the depth of immersion of the basepoints (ITs) of the dual semi-spherical indenter with a normal load of 425N. The Overload Immersion is the depth of immersion of the basepoints (ITs) of the bulbous indenter with an overload load of 525N (a 100N increase from the normal load). Pressures are averaged across all sensors within an elevation (in Figure 23, yellow sensors represent Elevation 1 (ITs), red sensors represent Elevation 2, blue sensors represent Elevation 3, and green sensors represent Elevation 4 (trochanters)). Pressures are measured and recorded under normal load and overload conditions. Two sizes of the dual semi-spherical indenters (large and small) and two loads (normal load and overload) to assess the ability of the cushion to adjust to changes in size and weight.

Results

Small Indenter Envelopment results can be seen in Tables 6, 8 & 10 and Figures 24, 26, 28-30 & 34-36. Large Indenter Envelopment results can be seen in Table 7, 9 & 11 and Figures 25, 27, 31-33 & 37-39.

Note: the G7 with Woven Air was tested only in the 6 air cell configuration.

Table 6. Small Indenter Envelopment Immersions averaged over three trials

	Thickness (mm)	Normal load Immersion (mm)	Overload Immersion (mm)
Woven Air	94	57	3
G7 Air (6 cell)	123	63	3
G7 Gel	115	63	3

Table 7. Large Indenter Envelopment Immersions averaged over three trials

	Thickness (mm)	Normal load Immersion (mm)	Overload Immersion (mm)
Woven Air	93	53	2
G7 Air (6 cell)	123	60	3
G7 Gel	114	60	3

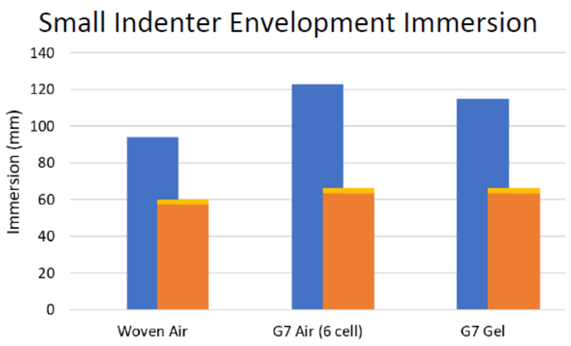


Figure 24. Normal load Immersion (orange), Overload Immersion (orange + yellow) and thickness (blue) with the small indenter

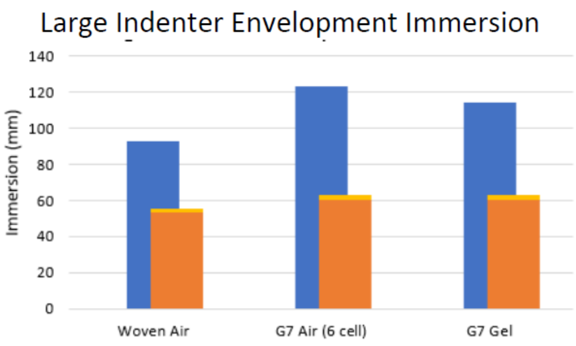


Figure 25. Normal load Immersion (orange), Overload Immersion (orange + yellow) and thickness (blue) with the large indenter

Table 8. Small Indenter Envelopment Normal Load Pressures Elevations 1-4 averaged over three trials

	Elevation 1 (mmHg)	Elevation 2 (mmHg)	Elevation 3 (mmHg)	Elevation 4 (mmHg)
Woven Air	58	59	78	123
G7 Air (6 cell)	41	57	50	96
G7 Gel	32	84	76	78

Table 9. Large Indenter Envelopment Normal Load Pressures Elevations 1-4 averaged over three trials

	Elevation 1 (mmHg)	Elevation 2 (mmHg)	Elevation 3 (mmHg)	Elevation 4 (mmHg)
Woven Air	62	50	67	114
G7 Air (6 cell)	56	55	30	101
G7 Gel	40	70	60	39

Table 10. Small Indenter Envelopment Overload Pressures Elevations 1-4 averaged over three trials

	Elevation 1 (mmHg)	Elevation 2 (mmHg)	Elevation 3 (mmHg)	Elevation 4 (mmHg)
Woven Air	78	78	97	142
G7 Air (6 cell)	57	76	65	112
G7 Gel	49	102	96	98

Table 11. Large Indenter Envelopment Overload Pressures Elevations 1-4 averaged over three trials

	Elevation 1 (mmHg)	Elevation 2 (mmHg)	Elevation 3 (mmHg)	Elevation 4 (mmHg)
Woven Air	77	69	83	154
G7 Air (6 cell)	68	71	40	123
G7 Gel	58	84	79	52

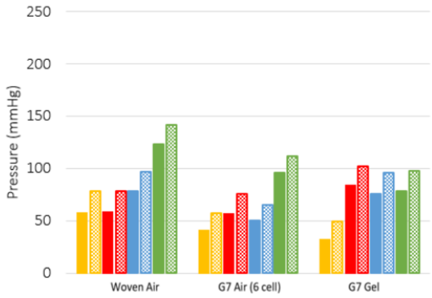


Figure 26. Pressures at elevations 1 (yellow), 2 (red), 3 (blue) and 4 (green) at Normal and Overload with the small indenter

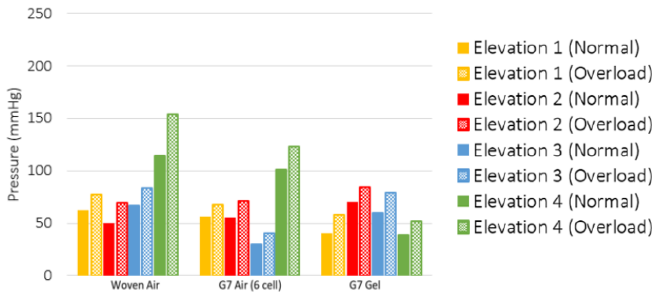


Figure 27. Pressures at elevations 1 (yellow), 2 (red), 3 (blue) and 4 (green) at Normal and Overload with the large indenter

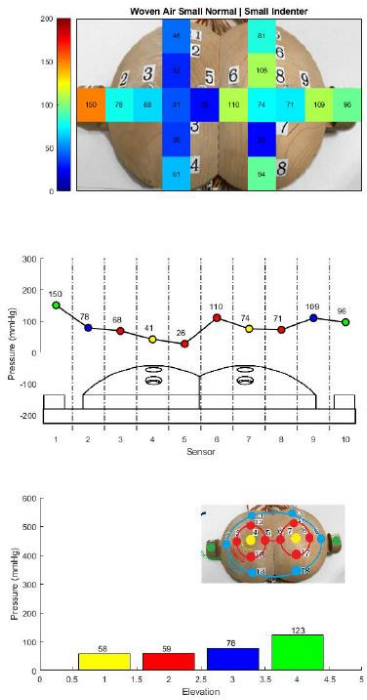


Figure 28. Envelopment pressure for the Woven Air under normal load with the small indenter

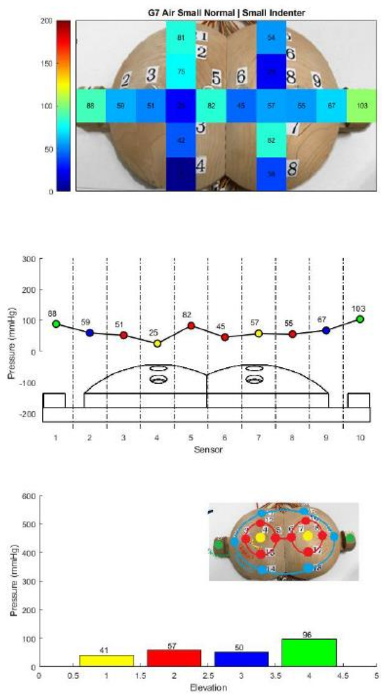


Figure 29. Envelopment pressure for the G7 Air (6 cell) under normal load with the small indenter

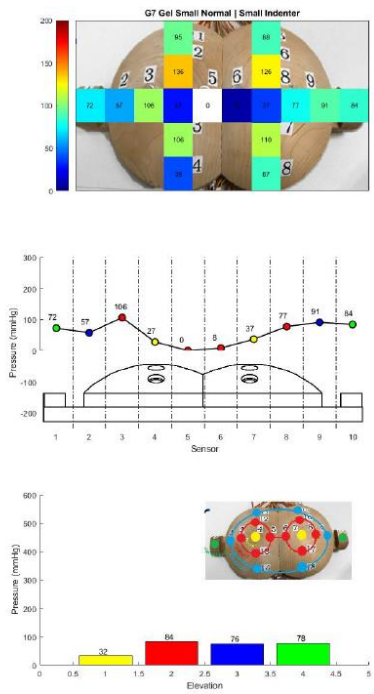
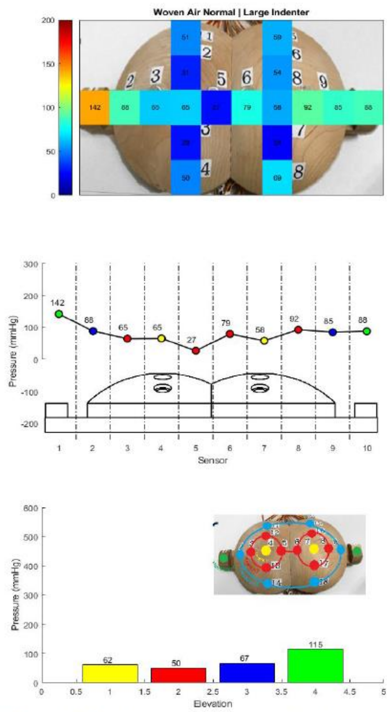
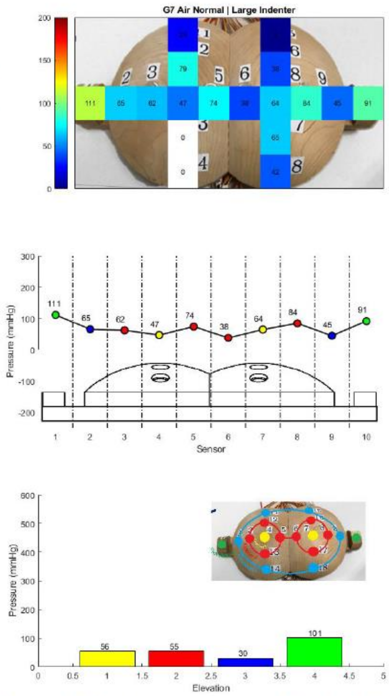


Figure 30. Envelopment pressure for the G7 Gel under normal load with the small indenter





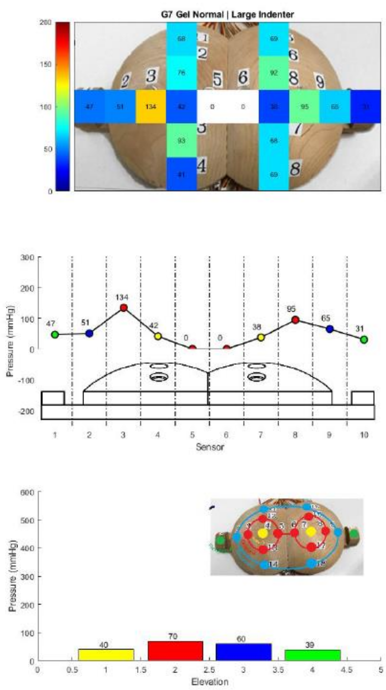
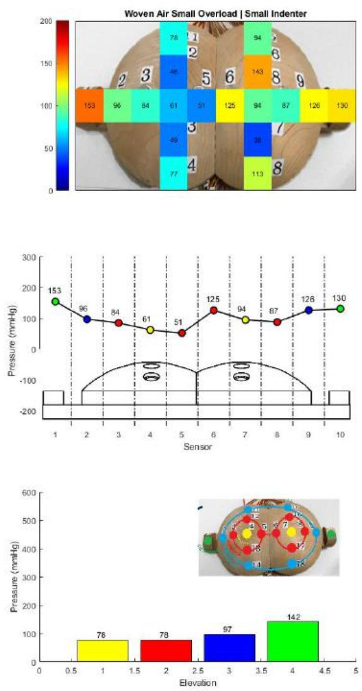
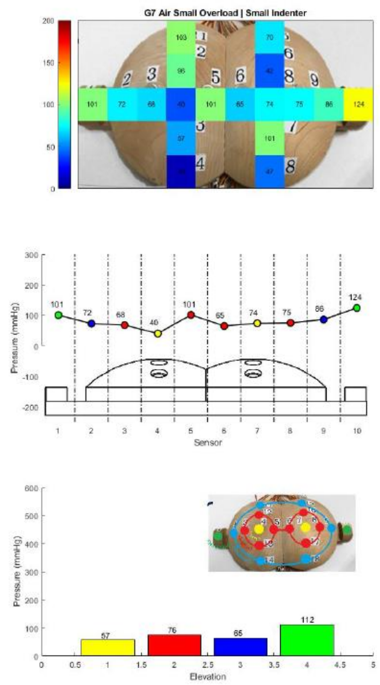


Figure 31. Envelopment pressure for the Woven Air under normal load with the large indenter

Figure 32. Envelopment pressure for the G7 Air (6 cell) under normal load with the large indenter

Figure 33. Envelopment pressure for the G7 Gel under normal load with the large indenter





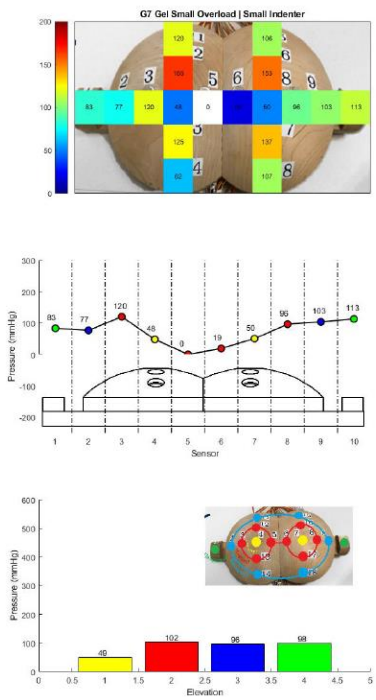


Figure 34. Envelopment pressure for the Woven Air under overload with the small indenter

Figure 35. Envelopment pressure for the G7 Air (6 cell) under overload with the small indenter

Figure 36. Envelopment pressure for the G7 Gel under overload with the small indenter

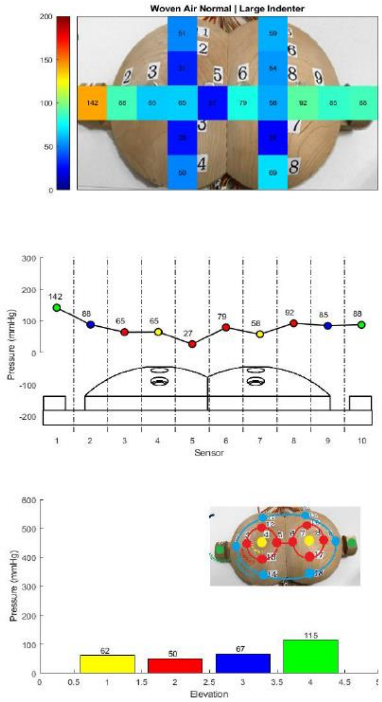


Figure 37. Envelopment pressure for the Woven Air under overload with the large indenter

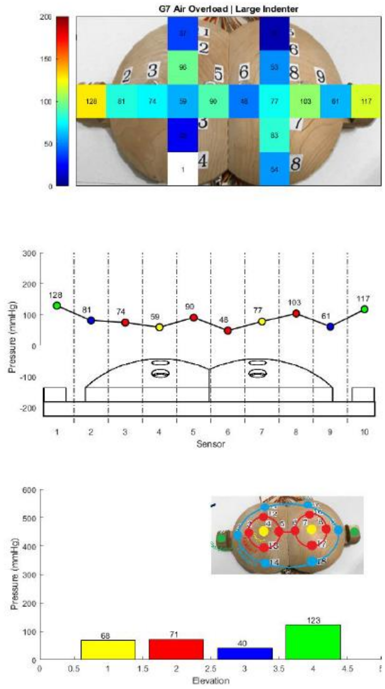


Figure 38. Envelopment pressure for the G7 Air (6 cell) under overload with the large indenter

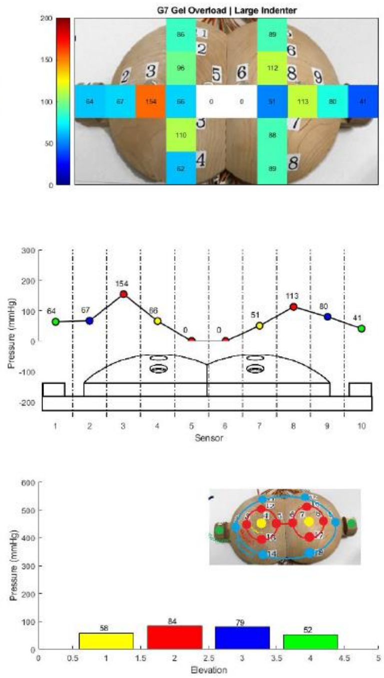


Figure 39. Envelopment pressure for the G7 Gel under overload with the large indenter

Observations and Conclusions

• All three cushions minimize load on Elevation 1 (Ischial Tuberosities).

• The G7 Gel cushion exhibited zero pressures in the gluteal cleft region and higher pressures at lateral sensor locations 3 and 8. This is consistent with the higher Peak Pressure Indices seen in Pressure Mapping results above, which also suggested less envelopment of the buttocks with this cushion.

• The Woven Air and G7 Air (6 cell) supported greater loads at Elevation 4 (trochanters).

• Relative to the 50 cushion cohort, all of the Rolapal cushions' immersions fall in the middle of the range.

A good pressure distribution is indicated by low pressures of similar magnitude across all elevations (good envelopment) or very low pressures/offloading at Elevation 1 (ischial tuberosities).

APPENDIX A: Pressure Mapping

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