Permobil
Scientific Report

Guidance to individualized cushion selection based on performance metrics

permobil

Guidance to individualized cushion selection based on performance metrics: a scientific report

Permobil Global
April 2023

Carla Nooijen, PhD
Senior Researcher, Group R&D, Scientific and Medical Affairs, Permobil
Human movement scientist, with a PhD degree in rehabilitation medicine

Kara Kopplin, B.Sc.Eng.
Director of Regulatory Science, Group R&D (Seating and Positioning), Permobil
Scientific committees: ANSI/RESNA Wheelchair and Related Seating Standards Committee (US Chair); ISO TC173 / SC1 / WG 11 Wheelchair Seating Standards (US Expert); EU CEN Wheelchair Standards (Elected Liaison with ISO); NPIAP Corporate Advisory Council (Panel member)

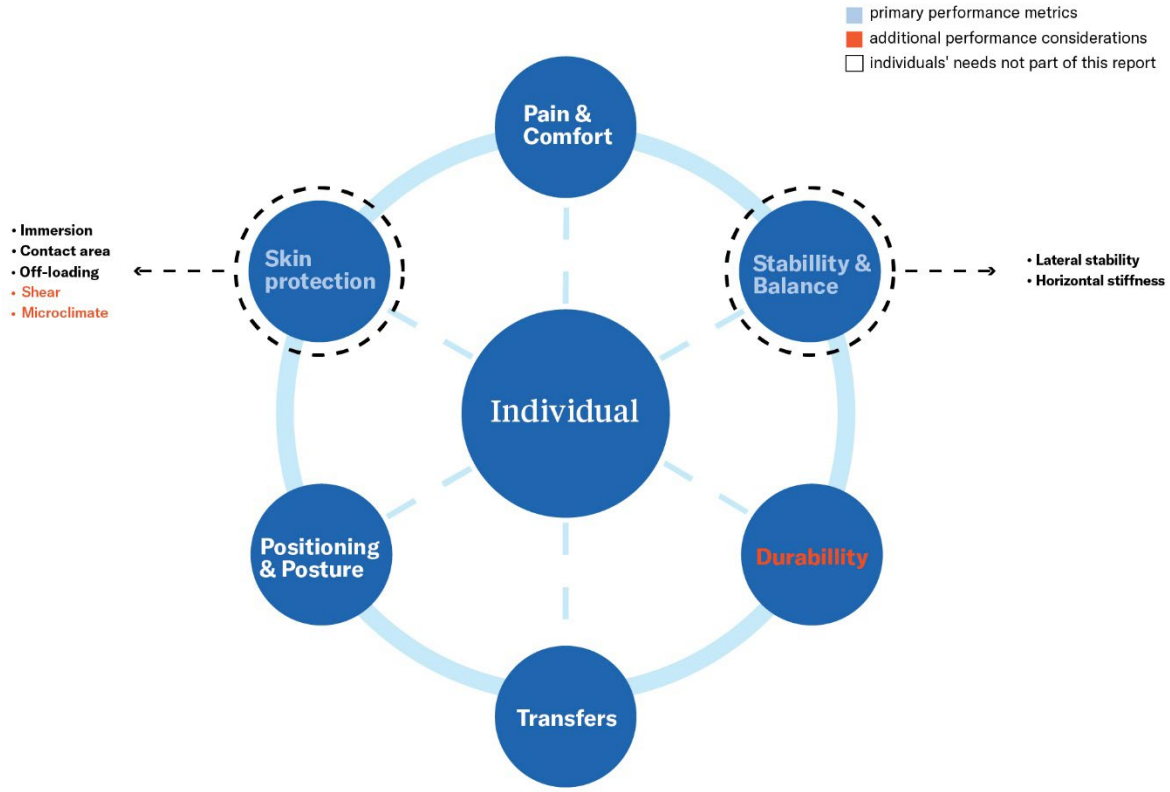
Nicole B. LaBerge, PT, ATP
Portfolio Marketing Manager of Seating and Positioning, Permobil Americas
Executive Board Member, Clinician Task Force

Table of contents

Summary

Considering the full range of individuals' needs when selecting a cushion

This scientific report contributes to filling the gaps between clinical decision making, individual need assessment and the lack of sufficient scientific evidence for cushion selection. The figure below presents an overview of individuals' needs to be considered when selecting a cushion. Highlighted in light blue are the primary performance considerations for skin protection and stability and balance. Highlighted in red are performance metrics that in this report were regarded as additional considerations. All remaining individuals' needs in white are important to consider but not part of this report.



Performance metrics based on ISO testing

The performance metrics for skin protection and stability & balance are based on results from ISO testing (International Organization for Standardization) published online November 2021 by the University of Pittsburgh's Rehabilitation Engineering Research Center (RERC) (wheelchairstandards.com). Primary performance metrics were chosen by using guidance from the Clinical Practice Guideline.[6] Using statistical parameters, and for each of the performance metrics, thresholds were determined to categorize cushions into lower priority, typical, or higher priority for individual needs. The primary performance metrics with thresholds are presented in the table below and allow to categorize any cushion for which data on these performance metrics are available.

Skin protection primary performance metrics thresholds

	Lower priority	Typical priority	Higher priority
Immersion ISO 16840-2:2018 Clause 11	<40 mm loaded contour depth	≥40 and ≤45 mm loaded contour depth	>45 mm loaded contour depth
Contact area ISO 16840-6:2015 Clause 14	<52346 mm^2 contact area	≥52346 mm^2 and ≤71276 mm^2 contact area	>71276 mm^2 mm contact area
Off-loading IT **ISO 16840-12:2021** (Non-IT pressure/total pressure)*100%	<84% off-loading	≥84% and ≤88% off-loading	>88% mm off-loading

Stability and balance primary performance metrics thresholds

Lateral stability ISO 16840-13:2021	<5.9° tilt angle after 60 sec	≥5.9° tilt angle and ≤4.2°tilt angle after 60 sec	>4.2° tilt angle after 60 sec
Horizontal stiffness / forward stability ISO 16840-2:2018 Annex C	<126 N peak force	≥126 N and ≤161 N peak force	>161 N peak force

*Test results performed with small and large indenter to be combined using same thresholds.

Results for skin protection and stability & balance per cushion

The results for the cushions manufactured by Permobil can be found below. All performance metrics are consciously presented in one table to enable you to consider these metrics together to understand the differences between cushions and also consider the individual's priority for these selected five key performance metrics.

Skin protection primary performance metrics categorizing cushions

	Lower priority	Typical priority	Higher priority
Immersion ISO 16840-2:2018 Clause 11	Comfort Express Comfort Foam	ROHO Hybrid Select ROHO Single Compartment Low Profile	Comfort Embrace Comfort M2 Comfort M2 with GlideWear Comfort Saddle ROHO Single Compartment High Profile ROHO MOSAIC ROHO QUADTRO SELECT High Profile
Contact Area ISO 16840-6:2015 Clause 14	Comfort Express Comfort Foam	Comfort Embrace Comfort M2 ROHO Single Compartment Low Profile ROHO MOSAIC ROHO Hybrid Select	Comfort M2 GlideWear Comfort Saddle ROHO Single Compartment High Profile ROHO QUADTRO SELECT High Profile
Off-loading IT ISO 16840-12:2021 (Non-IT pressure/total pressure)*100%)	Comfort Express Comfort Foam	Comfort Embrace Comfort M2 Comfort M2 GlideWear ROHO QUADTRO SELECT High Profile Dependent on indenter size: ROHO MOSAIC*	ROHO Single Compartment Low profile ROHO Single Compartment High profile Dependent on indenter size Comfort Saddle** ROHO Hybrid Select***

*Typical priority for large indenter, low priority for small indenter, **High priority for small indenter, low priority for large indenter, *** High priority for large indenter, typical priority for small indenter

Stability and balance primary performance metrics categorizing cushions

	Lower priority	Typical priority	Higher priority
Lateral stability ISO 16840-13:2021	ROHO Single Compartment High profile ROHO Single Compartment Low profile ROHO MOSAIC	Comfort Embrace Comfort M2 Comfort M2 with GlideWear Comfort Saddle ROHO QUADTRO SELECT High Profile	Comfort Express Comfort Foam ROHO Hybrid Select
Horizontal stiffness/forward stability ISO 16840-2:2018 Annex C	Comfort M2 with GlideWear ROHO Single Compartment High profile ROHO Single Compartment Low profile ROHO QUADTRO SELECT High Profile	ROHO Hybrid Select ROHO MOSAIC Comfort Company M2	Comfort Embrace Comfort Express Comfort Foam Comfort Saddle

Guidance on cushion performance

When considering the cushion choice for an individual, the presented results can serve as guidance with regards to skin protection and stability & balance. When this guide is used, one should be aware of the limitations, including that the current categorization is based on results of standardized testing in a laboratory setting without humans involved and is based on statistical parameters and therefore are not based on clinical outcomes.

1. Introduction

Recently, the University of Pittsburgh's Rehabilitation Engineering Research Center (RERC) published scientific results comparing performance metrics of approximately 50 cushions intended to redistribute pressure, provide postural support and/or provide skin protection. The data are available online via an Interactive Data Exploration Tool: wheelchairstandards.com). Among these cushions are 10 cushions manufactured by Permobil.

The results, however, do not allow a straightforward interpretation. In collaboration with the researchers at RERC, we have worked on a scientifically and clinically sound interpretation of the results. This report informs the reader of the analysis process, explains the suggested interpretation, and provides detailed results. Our goal is to provide this information and scientific discussion in a transparent and trustworthy manner.

1.1 Why this report was written

The purpose of this report is to provide insight and a summary of recent scientific results collected for multiple wheelchair cushions. When selecting a cushion for a seating system in a wheelchair, specific needs of the individual using the mobility device must always be considered and maintained at the center of the decision-making process. A clinician has multiple tools available to assist with the cushion selection process, however, there are limitations in that not all tools provide an evidence-based comparison. Although these approaches provide information, no single source should be used as the deciding factor when selecting a solution. Pressure injury risk assessment tools, such as the Braden scale or the Waterlow scale, can be helpful for identifying individuals that are at high risk for skin breakdown. However, one should not use only the scale, but also consider the individuals' activities, as well as personal and environmental characteristics.[1]

The available research studies on the effectiveness of cushions are difficult to compare as most report on outcomes from pressure mapping, which showed large variability between studies.[2,3] The optimal outcome to determine the effectiveness of cushions would be pressure injury occurrence, but this requires challenging large-scale studies and may pose ethical dilemmas as it requires at-risk populations to use cushions for longer periods of time that, by performance metrics, are known to be inferior.[2] The performance metrics as described in this report are therefore one of the few sources of evidence available that give insight into differences among a large range of cushions. This report was written to assist the individual who uses a mobility device, the clinician, and the provider to better understand the scientific results and how they can be used; it is not intended to be utilized as a cushion selection tool.

1.2 How this report can be used

As you read through this summary, it is important to note that the performance metric results are derived from pre-clinical testing. This testing is completed in a scientific research lab, with a standardized set up of all variables, without a human participant. Alongside each test description, you will see a clinical explanation of what these tests and results mean and how they may translate to the individuals' needs. This report can be used to get a better understanding of the differences and similarities in cushion performance metrics.

2. Background

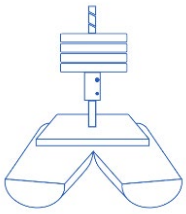
2.1 Intro to the ISO standards and Clinical Practice Guideline (CPG)

ISO Standards

The performance metrics that will be discussed are based on the International Organization for Standardization (ISO) standards. ISO is a global network of national standards bodies that publishes standardized procedures, processes, and test methods to solve global challenges. ISO Standards are internationally agreed upon by experts and can be considered a formula that describes the best way of doing something.[4]

Within the ISO structure are specific committees and working groups that develop laboratory tests for wheelchairs and wheelchair seating.[5] Participants are experts who have been nominated by their countries, and include engineers, clinicians, researchers, manufacturers, scientists, policy makers, academics and individuals using mobility devices. Consensus and publication of tests is achieved through several rounds of revision and international voting.

The ISO standards for cushions can be considered pre-clinical testing and consist of mechanical bench tests that measure cushion performance in a standardized way. Rather than having human participants, these tests are typically performed with an "indenter" that is pressed into the cushion.



The indenters are rigid forms, based on simplified body geometries, with specific dimensions and weight loads, typically representing a 50th percentile male. There are indenters shaped like simple geometric buttocks and thighs, indenters that are hemispheres to represent the buttocks alone, and cylinders to represent typical pelvic landmark locations and dimensions.

Although the indenters are simplifications, quite different than a human body, they remove the variations in size, weight, load, and position that occurs when human testing is conducted. Reducing and eliminating as many variables as possible, under controlled conditions and laboratory procedures, allows for a standardized comparison of performance metrics of different cushions, in a way that is objective, repeatable, and reproducible across laboratories.

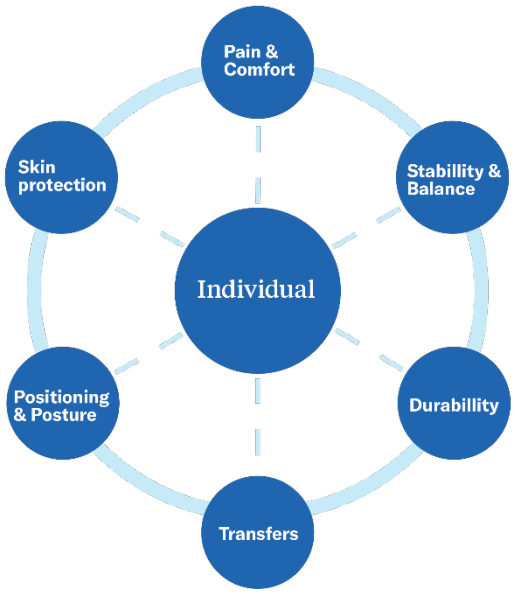
Clinical Practice Guideline (CPG) – Pressure Injuries

A Clinical Practice Guideline (CPG) for the prevention and treatment of pressure injuries was published in 2019.[6] This publication offers a clinical perspective that can be applied to the development and application of ISO tests. The ISO tests that were chosen to be discussed in this report correspond with specific CPG guidance for skin protection and stability.

The CPG was published in 2019 by international experts on pressure injury prevention from the United States (NPIAP), Europe (EPUAP) and Asia (PPPIA).[6] Over 250 international experts reviewed the evidence of over 3500 peer reviewed research studies and drafted recommendations on prevention and treatment of pressure injuries. The CPG includes the etiology of the wounds, patient risk factors, clinical care recommendations, interventions and healing strategies, and the role of support surfaces (including mattresses, overlays, and wheelchair cushions). Over 1000 stakeholders provided feedback, and the result was an international consensus on the best current practices, based on the state of the science and clinical experience.

2.2 Clinical overview

An individual that uses a wheeled mobility device has unique needs and considerations for their seating and positioning equipment (See Figure 1). Considering the entire spectrum of the International Classification of Functioning, Disability and Health (ICF) model[1], examples of considerations should specifically address the person's body functions and structures, health conditions, activities and participation, personal factors and the environment that they live in.[1] Because of an individual's uniqueness, it should not be assumed that one cushion type will meet every single individuals' needs.



Clinical Overview

Every individual has their own specific seating and positioning needs.

Their environment as well as their skin protection, posture, stability and balance, pain or comfort should all be considered when selecting a cushion.

Transfer ability and the durability of the cushion should also be assessed.

Figure 1. Individuals' needs for selection of a cushion.

When looking at cushion performance metrics and CPG Guidelines it is important to acknowledge the information and data and then, the clinician can discuss with the person who uses the wheeled mobility device, what is most important to them.

There are three major considerations when interpreting cushion performance metrics from ISO testing. First, results are limited to providing performance characteristics with regards to skin protection, stability and balance, and durability. Results on skin protection and stability and balance will be shared in this report, and considerations on durability will be given. All remaining needs for the individual are important to also consider, but information collected from other sources is not the focus in this report. A second consideration is that multiple cushions could have similar test results. A third consideration is that the individual that is seated on the cushion surface will have different feedback based on their experience of actually sitting on the cushion, compared to the data generated through ISO testing in a standardized test environment with a mechanical 'indenter'. Therefore, an extensive overview of all the individual's needs as well as the personal feedback while sitting on the cushion should play a key role when making any final product decisions.

2.3 University of Pittsburgh's Rehabilitation Engineering Research Center (RERC) data

The RERC has been heavily involved in the development and application of standards for wheelchairs and wheelchair seating and includes researchers who hold several leadership roles at national and

international levels. They likewise are leaders in the National Pressure Injury Advisory Panel (NPIAP), bridging wheelchair engineering knowledge with the clinical understanding of pressure injuries and strategies for prevention.

In 2017, the Wheelchair and Cushion Standards group at University of Pittsburgh was awarded a RERC grant to evaluate and further develop RESNA (Rehab Engineering and Assistive Technology Society of North America) and ISO performance standards. They applied a subset of test methods from the ISO 16840 standard suite to a diverse cohort of approximately 50 cushions from multiple manufacturers, that were chosen by the University of Pittsburgh researchers. Permobil was asked to contribute specific cushions as part of this national scientific testing effort. The results of this testing are presented in the *Interactive Data Exploration Tool: wheelchairstandards.com*

3. Methodology

Figure 2 provides an overview of considerations for individuals' needs for selecting a cushion. Highlighted in blue are the primary performance metrics described in this report, and highlighted in red are additional performance considerations. All remaining individuals' needs in white are important to consider as well but will not be described in this report.

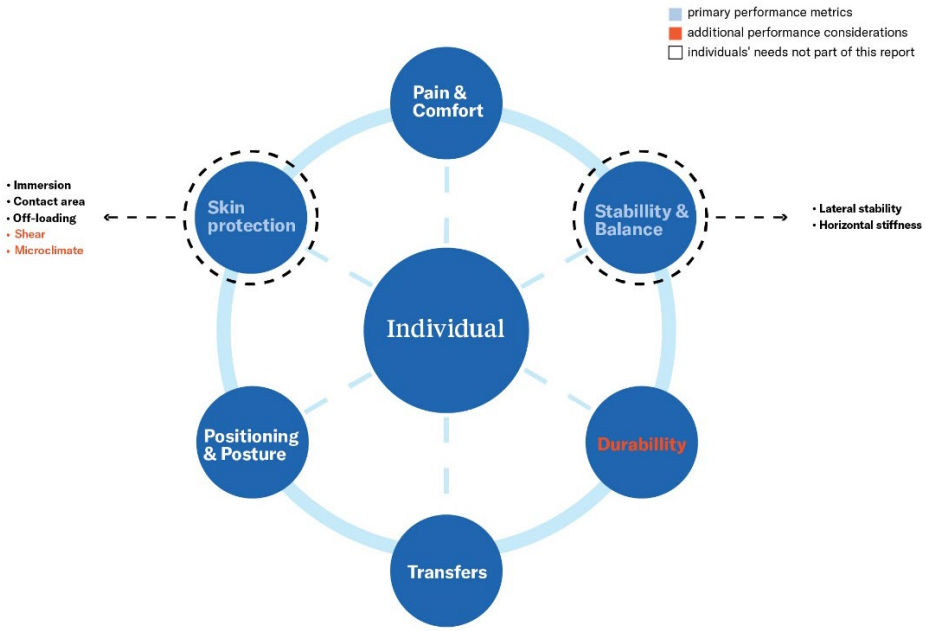


Figure 2. Individuals' needs for selection a cushion, with highlighted in blue the primary performance metrics and in red additional considerations described in this report.

3.1. Selection of primary and secondary performance metrics

The primary performance metrics that were chosen from the ISO test results provided by the RERC research team were selected for their connection to the specific CPG guidance on skin protection and also stability and balance.[6] Focus was therefore on the selection of those measures that give most insight into how the cushion responds to the individual.

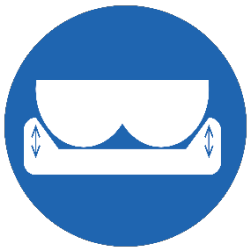
Other performance metrics were considered secondary. They quantify specific mechanical properties, such as force deflection, hysteresis, and impact damping; but these values do not give as much insight overall into how the cushion will respond to the individual and environment.

3.2. Explanation of primary performance metrics

The primary performance metrics for skin protection are immersion (loaded contour depth), contact area (from pressure mapping), and off-loading (from envelopment pressure measurements). The primary performance metrics for cushion stability and balance include lateral stability (tilt angle) and horizontal stiffness (peak force). Summarized results for the primary performance metrics are presented in the results section, and detailed results for each performance metric including thresholds are presented in appendix B.

<u>Skin protection</u>

For skin protection, cushion construction achieves pressure redistribution through the methods of immersion/envelopment and/or redirection/offloading.[6]

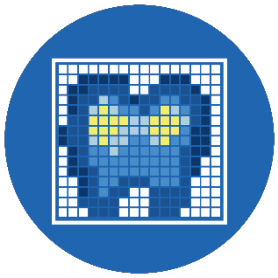


Immersion

Immersion is measured by the loaded contour depth test (ISO 16840-2:2018 Clause 11). This performance metric evaluates the cushion's ability to immerse the buttocks and protect the bony prominences. This test looks at the depth of immersion of the basepoints, or the Ischial Tuberosities (ITs), of a cushion loading indenter. In addition to the loaded contour depth, overload deflection (33% and 66%) is measured within this test. As the range of these values is relatively small (2 to 8 mm for 33% overload deflection) and values are presented with zero decimal precision, overload deflection could not be used to categorize cushions using statistical parameters and was therefore excluded.

Immersion
Immersion is how deeply the body sinks into a cushion. A higher Loaded Contour Depth indicates more immersion into the cushion and distribution of pressure on the soft tissue vs the bony prominences.

In the US, one of the largest funding agencies (Centers for Medicare and Medicaid Services, CMS) has adopted a modification of the loaded contour depth test to qualify cushions as providing "skin protection" by demonstrating at least 40 mm of loaded contour depth. It is important to note that ISO standardized tests are voluntary, and only become mandatory when a regulatory body, funding body or healthcare system in a country or region requires them.



Contact area

Contact area is measured by pressure mapping (ISO 16840-6:2015 Clause 14). This test utilizes interface pressure measurements to assess the magnitude and distribution of pressure on a loaded cushion. Metrics are recorded for 60 seconds after the cushion is loaded with the indenter. The contact area for pressure redistribution is the total load bearing area. In addition to contact area, peak pressure index right and left base zone (mmHg) and the dispersion index are outcomes of this test, but they are considered secondary performance metric in this report.

Contact area

The test reveals how much contact is being made between the cushion and the individual. The goal is to achieve as much contact area as possible to promote greater pressure redistribution.

Pressure mapping is a common tool utilized within the clinical setting, to assess peak pressure and overall pressure distribution of the person while seated on the support surface. However, there are concerns with regards to the reliability of pressure mapping.[3] Looking at the data and the results of peak pressure index presented at wheelchairstandards.home/pressure-mapping, this limited reliability is also reflected in relatively large differences for some cushions between peak pressure index right and left, e.g. more than 20 mmHg difference for Cushion AY, D, AI, and AC (where a similar result would be expected). Furthermore, there is a risk that these data may be misinterpreted: the data are pre-clinical data using indenters and it does not consider the individual's body composition. The setup of the wheelchair including the seating components and the overall positioning of the person will directly affect peak pressures. Therefore, only contact area was chosen as a primary performance metric in this report. The dispersion index is part of the secondary outcome measures presented in Appendix C. Peak pressure index is not included in this report because of the unexplainable differences between right and left as mentioned above. We do support that this tool should continue to be used when assisting the individual with selecting their cushion. It needs to be noted that using pressure mapping as the only means to select a cushion, without considering all other variables that can contribute to the pressure results, as well as other performance metrics and individual's needs, could result in sub optimal recommendations.

Off-loading

Off-loading is measured by an envelopment pressure test (ISO 16840-12:2021) and evaluates a cushion's ability to distribute the load of the seated individual. The data reveals how this is accomplished, through conforming to the contour of the body, immersing and enveloping the buttocks, and/or distributing the load of the person to other regions of the body (such as lowering the load at the ITs while increasing at the greater trochanters or GTs). The pressure averages at each of the four elevations on the indenter provides

Off-loading

Offloading is described as taking the pressure from one area, often the ITs, and placing additional pressure on the soft tissues or the GTs to decrease the risk of skin breakdown.

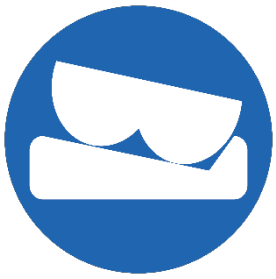
The cushion allows for immersion and then additionally contacts around the individual's contours to provide envelopment.

information on the cushion's ability to redistribute forces. Similar pressure values at each elevation indicates good envelopment. Tests were performed with different indenter sizes which can give an indication of the cushion's ability to adjust or adapt to different body types.

As a primary performance metric, the pressure of the ITs (sensors 4 and 7) was considered as a percentage of the total pressure on all areas (sensors 1 – 18). An offloading value was represented as the percentage of pressure on other regions (Non-IT pressure/total pressure)*100%) or ((Sensors 1-18) – (sensors 4,7)) / (Sensors 1-18). For mattresses and overlays, relative measures derived from the envelopment pressure test have shown to be valid and reliable.[7]

Using a combined measure of the ITs and the GTs as a percentage of the total pressure on all areas was also explored. However, this did not lead to a valid categorization of the cushions. For example, for cushion D the pressure on the ITs was relatively high compared to the total pressure, but no pressure on the GTs was measured. Combined results would, however, categorize this cushion as performing well for off-loading.

Stability and balance

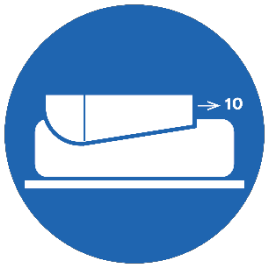


Lateral stability

Lateral stability (ISO 16840-13:2021) is a test that characterizes a cushion's ability to resist lateral leans. The measurement of the average lateral tilt angle reveals the stability the cushion may provide during side-to-side movement. The change in orientation of the indenter after a lateral shift in the center of mass is measured at 10 seconds increments for 60 seconds following the shift. As a primary performance metric, we report on the average tilt angle after 60 seconds.

Lateral Stability

A more stable cushion while the individual is leaning can allow for better functionality and potential less risk of falling from a loss of balance.



Horizontal stiffness

Horizontal stiffness (ISO 16840-2:2018 Annex C) is a test to evaluate the cushion's response to slight horizontal movements in the forward direction. This test helps to describe the smaller movements and the response of the cushion during functional activities. It is an important consideration when assessing the stability that a person may require. The bulk forces that are measured are the shear forces that result from the interaction between the full buttock and thigh representations of the indenter and the cushion material, contours, and reactions to force. This metric was considered as an indicator of shear forces that aid in stability by overall helping to hold the individual in place. From the standpoint of shear and pressure injury prevention, we consider the

Horizontal Stiffness

How much force is required to slide forward on the cushion when seated is the horizontal stiffness.

A higher force indicates more stability and lower risk to slide forward.

data that can be collected through a small pressure sensor in the region of interest (at the ITs) to be a better, more localized assessment of the shear force that could lead to injury in that area. This will be discussed in the considerations in section 5.1.

Peak force was included as a primary performance metric, and final force as a secondary metric. For simplicity, and as an understanding of the highest reactive force involved, we selected peak force as the primary measure.

3.3. Explanation of secondary performance metrics

Short descriptions of all secondary performance metrics will be given below. More details are provided on the RERC website *(Interactive Data Exploration Tool: wheelchairstandards.com)*. The results of the secondary performance metrics are described in Appendix C.

Impact Damping (ISO 16840-2:2018 Clause 9) is a test that reports on initial impact acceleration and an impact ratio of the second impact to the initial, that can help to evaluate a cushion's ability to reduce impact loading on tissues and help maintain postural stability when performing tasks such as going off a curb. While this test indicates the way the cushion material responds to vibration, the entire wheelchair system contributes to transferring or damping vibrations (wheelchair frame, casters, forks, etc).[8] For this reason, it was considered a secondary performance metric.

Hysteresis (ISO 16840-2:2018 Clause 14) is a test to evaluate the cushion's ability to consistently provide support during a cycle of loading and unloading (at 250 N and 500 N). The larger the hysteresis, the lower the ability of the cushion to maintain support during loading and unloading, or the greater the tendency to conform to the individual and maintain the contour shape.

10% Force Deflection (ISO 16840-6:2015 Clause 20) is a test to evaluate a cushion's ability to "cushion" or elastically deform by measuring the force necessary to produce a deflection of 10% of the cushion thickness. A cushion that requires a lower average force to produce a 10% compression of its total thickness has a less stiff, more compliant cushion surface. A higher average force may indicate a harder, stiffer cushion surface.

Both Hysteresis and 10% Force Deflection characterize the cushion medium itself and were therefore chosen as a secondary performance metrics.

Envelopment - immersion

Envelopment-immersion (ISO 16840-12:2021)
The loaded contour depth test previously described provides a measure of the ability of the pelvis to immerse into a cushion and be supported, as simulated by an indenter with simple geometric cylinders. The envelopment-immersion test follows the same approach but utilizes a buttock shaped indenter. This was chosen as a secondary performance metric for multiple reasons. Secondary performance metrics include nominal load and not overload because, comparable to immersion overload described earlier, the range of these values is small, and values are presented with zero decimal precision and could not be used to categorize cushions using statistical parameters. First, results of this test and the loaded contour depth test were very similar with the difference that while using the 40 mm threshold for immersion, almost all tests would be categorized as high performers in the envelopment-immersion test and therefore did not contribute to differentiating between cushions. Second, it can be debated that individuals who use a wheelchair typically do not have this

rounded seated anatomy and it may be better to assume a “worst case” simulation that the loaded contour depth indenter provides.

3.4 Data analytics

Representative set of cushions
The cushions chosen by RERC consist of a diverse cohort of 50 cushions. The cushions that were tested represented various manufacturers, materials, and designs. These cushions serve as a good representation of the different types of cushions that are available in 2022. As this can therefore be seen as a representative data set, we deemed it possible to categorize the cushions into different categories using statistical parameters.

Not advised to individually rank cushions
RERC presented their data in bar charts. See Figure 3 for an example of how the data is presented for contact area. The current understanding of the clinical implications of the different performance metrics and the size of each individual bar in this graph is limited for the majority of the metrics. Although actual thresholds are not necessarily known, directional or relative performance of the proposed measurement variables is better understood. For example, specific thresholds of pressure have not been identified, but clinical trials have shown that lower pressures are associated with lower levels of tissue damage.[9]

We therefore do not feel confident to interpret all variations in magnitude as indicating better or worse performance. Although some cushions can rank a few places higher than others, the absolute differences in contact areas between cushions can be rather small and therefore are not likely to make a large difference for the individual. Looking e.g., at the middle of the graph, cushion O ranks five places higher than cushion R but the absolute difference between the cushions in contact area seems rather small 63221 vs 61616 mm^2), which is a difference of less than 3%. Therefore, instead of individually ranking the cushions, a broader categorization was chosen into three categories linked to the importance of each performance metric to the individual: lower priority, typical, and higher priority for the individual for each performance metric.

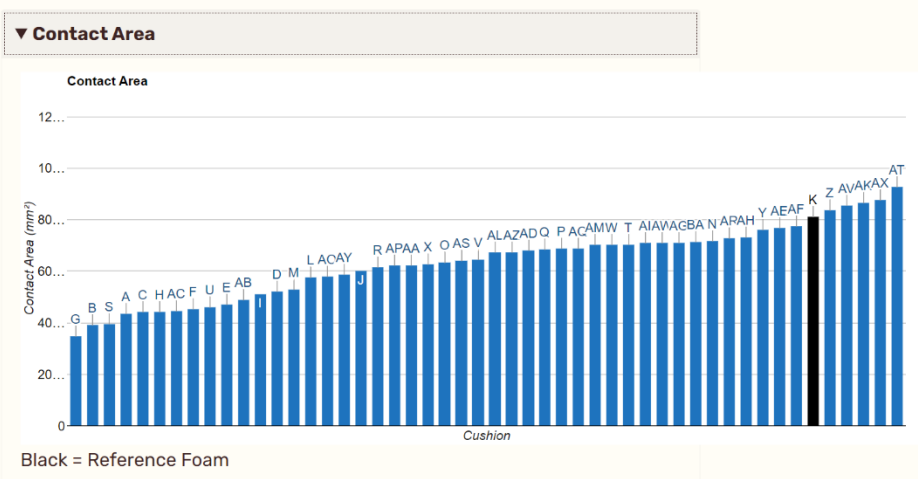
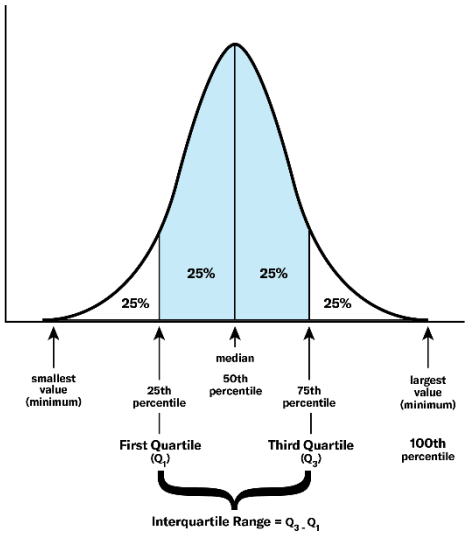


Figure 3. Data in bar chart for contact area results as presented by RERC

Thresholds

There are currently no clinical thresholds available to categorize into the three defined categories, for example the minimum desired contact area for a certain individual is unknown especially since every individual has a unique shape and size. An exception to this is immersion as measured by loaded contour depth. The anthropometrics of the pelvis require immersion and/or a pre contoured shape for load to be transferred from the inferior position of the ITs (assuming there is no asymmetry in the pelvis) to other load bearing anatomical surfaces (e.g. buttocks and thighs). The depth of immersion and contour is in the range of 40-45 mm (1.6 to 1.7 inches) for most individuals.[6,10] Therefore, this has been used to define thresholds for immersion into lower priority for immersion (<40 mm), typical immersion needs (≥40 and ≤45 mm), and higher priority for immersion >45 mm. The cut-off has been used both for the primary performance metric immersion as measured by loaded contour depth, and nominal load immersion from envelopment immersion.

For all performance metrics except immersion, thresholds have been defined based on the median (middle of the data) and interquartile range (measure of the spread of the data, also called the mid spread), see figure to the right. The interquartile range around the median (or second quartile) includes the middle category of "typical needs". By the nature of these statistical measures, this category contains 50% of the tested cushions. The minimum to the first quartile (Q1) defines the category "lower priority" (<Q1) and the third quartile (Q3) to the maximum value defines the "higher priority" category (>Q3).



For performance metrics that were both performed with a smaller and a larger indenter, including IT off-loading, results of both measurements were combined, and the cushion was categorized in the "best case" category with the note that the results were dependent on indenter size. Thresholds were similar, except for the Q3 threshold which was 88% of IT loading with the large indenter and 89% with the small indenter. For simplicity, a threshold of 88% was used in both cases.

To define these categories, the RERC research team has kindly provided the additional statistics of the available data needed to set the thresholds. Medians with interquartile ranges were chosen rather than means with standard deviation, because this allows for the same number of cushions to be categorized in each quartile, whereas when the data does not have a normal distribution, using data means leads to unequal lower and higher priority categories. Furthermore, the spread of the data is large and therefore standard deviations would lead to one rather large "typical" category (>50% of cushions for most performance metrics) which would make it difficult to differentiate between different cushions.

Thresholds for all primary and secondary performance metrics can be found in Appendix B and C. This allows for comparing cushions not listed in the current report, by simply placing the performance metric results in the scheme with presented thresholds. In these results, the value for reference cushion K is also listed. This reference cushion K was chosen by RERC to be a simple foam cushion (a 3" thick, high density polyurethane foam cushion with a 25% IFD of 170 N and 65% IFD of 320 N that was enclosed in a cover with a 2-way stretch nylon/spandex top and non-slip polyester

bottom). In our main overview of results, the reference cushion K was not included for ease of comparison between actual cushions available.

Limitations

It is important to realize that the current categorization for the majority of performance metrics is based on statistical parameters and therefore not relatable to a direct clinical outcome. Furthermore, the categorization does not allow for insight into those cushions that were borderline to one category or the other. Therefore, results do need to be interpreted with caution.

Permobil cushions included in the RERC Data set

Comfort Embrace Zero Elevation with GlideWear *(Comfort-Tek cover)*
Comfort Express Comfort Foam *(Standard cover)*
Comfort M2 *(Stretch-air cover)*
Comfort M2 with GlideWear *(Stretch-air cover)*
Comfort Saddle *(Standard cover)*
ROHO Hybrid Select *(Standard cover) Locked*
ROHO MOSAIC *(Standard cover)*
ROHO QUADTRO SELECT High Profile *(Standard cover) Locked*
ROHO Single Compartment Low Profile *(Standard cover)*
ROHO Single Compartment High Profile *(Standard cover)*

4. Results

Results of the primary performance metrics are presented for all 10 cushions manufactured by Permobil that were included in the testing. The Permobil cushions that were selected by RERC are highlighted in the box. In the RERC results, the individual cushions have been blinded, so the decoder for all cushions included in this report can be found in Appendix A. As stressed earlier, the performance metrics should never be considered separately but instead, the whole spectrum of the individual's needs (Figure 1) should be taken into consideration.

4.1. Thresholds

The primary performance metrics with thresholds are presented in the table below and allow categorization of any cushion with data on these performance metrics**.**

Skin protection primary performance metrics thresholds

	Lower priority	Typical priority	Higher priority
Immersion ISO 16840-2:2018 Clause 11	<40 mm loaded contour depth	≥40 and ≤45 mm loaded contour depth	>45 mm loaded contour depth
Contact area ISO 16840-6:2015 Clause 14	<52346 mm^2 contact area	≥52346 mm^2 and ≤71276 mm^2 contact area	>71276 mm^2 mm contact area
Off-loading IT ISO 16840-12:2021 (Non-IT pressure/total pressure)*100%	<84% off-loading	≥84% and ≤88% off-loading	>88% mm off-loading

Stability and balance primary performance metrics thresholds

Lateral stability ISO 16840-13:2021	<5.9° tilt angle after 60 sec	≥5.9° tilt angle and ≤4.2°tilt angle after 60 sec	>4.2° tilt angle after 60 sec
Horizontal stiffness / forward stability ISO 16840-2:2018 Annex C	<126 N peak force	≥126 N and ≤161 N peak force	>161 N peak force

*Test results performed with small and large indenter to be combined using same thresholds.

4.2. Results for Permobil cushions

The results for the primary outcomes of skin protection (immersion, contact area and off-loading) are summarized in the table below. The performance metrics for skin protection are consciously presented in one table. These metrics should be considered together in order to understand the differences between cushions when assessing the individual's priority for these three key performance metrics. Results and thresholds for each skin protection performance metric can be found in Appendix B.

Skin protection primary performance metrics categorizing cushions

	Lower priority	Typical priority	Higher priority
Immersion ISO 16840-2:2018 Clause 11	Comfort Express Comfort Foam	ROHO Hybrid Select ROHO Single Compartment Low Profile	Comfort Embrace Comfort M2 Comfort M2 with GlideWear Comfort Saddle ROHO Single Compartment High Profile ROHO MOSAIC ROHO QUADTRO SELECT High Profile
Contact Area ISO 16840-6:2015 Clause 14	Comfort Express Comfort Foam	Comfort Embrace Comfort M2 ROHO Single Compartment Low Profile ROHO MOSAIC ROHO Hybrid Select	Comfort M2 GlideWear Comfort Saddle ROHO Single Compartment High Profile ROHO QUADTRO SELECT High Profile
Off-loading IT ISO 16840-12:2021 (Non-IT pressure/total pressure)*100%)	Comfort Express Comfort Foam	Comfort Embrace Comfort M2 Comfort M2 GlideWear ROHO QUADTRO SELECT High Profile Dependent on indenter size: ROHO MOSAIC*	ROHO Single Compartment Low profile ROHO Single Compartment High profile Dependent on indenter size Comfort Saddle** ROHO Hybrid Select***

*Typical priority for large indenter, low priority for small indenter, **High priority for small indenter, low priority for large indenter, *** High priority for large indenter, typical priority for small indenter

The results for the primary outcomes for stability & balance (lateral stability and horizontal stiffness) are summarized in the table below. The performance metrics are consciously presented in one table. These metrics should be considered together in order to understand the differences between cushions for stability and balance when assessing the individuals' priority for these two key performance metrics. Results and thresholds for each stability and balance performance metric can be found in Appendix B.

Stability and balance primary performance metrics categorizing cushions

	Lower priority	Typical priority	Higher priority
Lateral stability ISO 16840-13:2021	ROHO Single Compartment High profile ROHO Single Compartment Low profile ROHO MOSAIC	Comfort Embrace Comfort M2 Comfort M2 with GlideWear Comfort Saddle ROHO QUADTRO SELECT High Profile	Comfort Express Comfort Foam ROHO Hybrid Select
Horizontal stiffness/forward stability ISO 16840-2:2018 Annex C	Comfort M2 with GlideWear ROHO Single Compartment High profile ROHO Single Compartment Low profile ROHO QUADTRO SELECT High Profile	ROHO Hybrid Select ROHO MOSAIC Comfort Company M2	Comfort Embrace Comfort Express Comfort Foam Comfort Saddle

5. Additional considerations

5.1 Shear

When the body is in contact with a supporting surface, such as a wheelchair cushion or mattress, both normal forces and shear forces are generated between the body and the support. As a result, the loaded soft tissues, including skin and deeper tissues (e.g., adipose tissue), will distort and deform, resulting in stress and strain within the tissues. It's not just about the overall external pressure from the normal/downward forces, the forces involved when someone is seated are complex and multidirectional, with compression, shear, and tension all distorting the tissues.[6] The measurement of shear forces, stresses, and strains is of great clinical and technical interest since shear is known to contribute to the development of pressure injuries.[6]

Shear Force

Shear can be described as the tissue gripping force.

The test reveals the potential of the cushion interaction with the body to distort/deform the tissue.

Lower shear forces to minimize the tissue distortion/deformation and reduce risk of pressure injury.

There is currently no ISO standardized test for measuring localized interface shear forces for wheelchair cushions. Different efforts are ongoing to develop shear measurements.[11,12] For example, the RERC research team has utilized a sensor that can measure interface shear forces in a small area. In addition to the horizontal stiffness test, which gives an idea of the overall "bulk" shear forces involved across the seated body and is influenced by the cushion contours and interface materials, the addition of a small shear force sensor to the critical region of interest (under the IT location) could potentially provide a better understanding of local shear.

The current understanding of shear is limited, but potentially shear forces can be reduced by certain cushion and cover designs. How shear performance metrics differ between cushions and covers is currently not well understood and therefore more research is necessary.

5.2 Durability and Aging

Wheelchair seat cushions are prescribed based on their ability to perform under a range of circumstances, from intermittent use to robust sports use, and use by those with regular incontinence. Each application presents different conditions that can change the performance of the cushion and can expose the individual to hidden risks. Standards for the evaluation of wheelchair cushions under a wide range of conditions are paramount.

Durability and Aging

This part of ISO 16840 provides a set of tests that simulate wear and tear, which can be useful to validate warranty claims and to provide information about product, life, and performance limitations associated with product use.

There is a durability/aging standard (ISO 16840-6:2015) which is based on a simulated use and determination of the changes inproperties of seat cushions. This test characterizes the changes in physical and mechanical properties of seat cushions based on their age and use. The standard offers a suite of simulated aging methods, not all of which will be appropriate for all cushions, and therefore, the manufacturer is to determine which are appropriate for their cushion construction and use. It is designed to provide a close approximation of the changes that have been observed to occur

over time. The protocol consists of performing tests to characterize the properties of a new cushion, subjecting the cushion to multiple simulated aging processes, then re-testing the cushion proprieties. Changes that occur are reported.

The RERC team performed additional analysis through the application of this ISO standard. They applied two rounds of aging challenges on a selection of performance metrics reporting on the before and after results so that the reader can observe the relative performance changes that occurred. They concluded that aging significantly decreased cushion performance, and thereby increased an individual's risk of pressure injuries.[13]

It is important to be aware that cushion properties will change over time. However, this is not the focused, immediate need of the individual and should instead be a tertiary consideration. Therefore, the durability and aging results of the cushions are not represented in this report.

5.3 Microclimate

Another risk factor for pressure injuries is the microclimate of the skin, or rather, the localized temperature, humidity, and airflow in the region of interest. Although the characteristics of an optimal microclimate are still a matter of debate and ongoing research, it is known that with an increase in temperature and humidity, the skin becomes more vulnerable to damage.[14] ISO standards for microclimate are currently under development and more research is necessary.

6. Conclusions

One single, specific performance metric or clinical test should never be used as a cushion selector tool. A seating solution for the individual can only be successfully chosen when a comprehensive approach is analyzed and understood. The individual's lifestyle and personal preferences are important considerations, and the identified needs for cushion selection include skin protection, stability and balance, pain and comfort, positioning and posture, transfer method and durability.

This scientific report provides an overview of cushion performance metrics derived from ISO testing for two of these needs: skin protection and stability and balance. For skin protection, the combined use of three performance metrics is suggested: immersion (loaded contour depth), contact area (from pressure mapping) and off-loading (envelopment). For stability and balance, the combined use of two performance metrics is suggested: lateral stability and horizontal stiffness.

The presented results can serve as guidance when considering any of the tested cushions. The guidance is given by categorizing each cushion according to the individual's priority for each performance metric: lower priority, typical priority, or higher priority. The results and threshold also allow for categorization of any other cushion for which these performance metrics are available.

When this guidance is used, one should be aware of the limitations. The current categorization is limited to results of standardized testing in a laboratory setting without humans involved and the categorization for all performance metrics except immersion is based on statistical parameters and not clinical outcomes.

References

1. WHO. ICF model. https://www.who.int/standards/classifications/international-classification-of-functioning-disability-and-health.

2. Damiao J, Gentry T. A systematic review of the effectiveness of pressure relieving cushions in reducing pressure injury. *Assist Technol*. Published online February 4, 2022:1-5. doi:10.1080/10400435.2021.2010148

3. He C, Shi P. Interface pressure reduction effects of wheelchair cushions in individuals with spinal cord injury: a rapid review. *Disabil Rehabil*. 2022;44(6):827-834. doi:10.1080/09638288.2020.1782487

4. International Organization for Standardization (ISO). https://www.iso.org/about-us.html.

5. International Organization for Standardization (ISO). *ISO 16840, Wheelchair Seating – Parts 1-14. International Organization for Standardization*.

6. European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel, Pan Pacific Pressure Injury Alliance. *Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline. The International Guideline*.; 2019.

7. *RESNA SS-1:2019 – American National Standard for Support Surfaces Volume 1: Requirements and Test Methods for Full Body Support Surfaces*.

8. Misch JP, Liu Y, Sprigle S. Effect of wheels, casters and forks on vibration attenuation and propulsion cost of manual wheelchairs. *IEEE Trans Neural Syst Rehabil Eng*. 2022;PP(Xx):1. doi:10.1109/TNSRE.2022.3205507

9. Brienza DM, Karg PE, Jo Geyer M, Kelsey S, Trefler E. The relationship between pressure ulcer incidence and buttock-seat cushion interface pressure in at-risk elderly wheelchair users. *Arch Phys Med Rehabil*. 2001;82(4):529-533. doi:10.1053/apmr.2001.21854

10. Sprigle S, Press L. Reliability of the ISO wheelchair cushion test for loaded contour depth. *Assist Technol*. 2003;15(2):145-150. doi:10.1080/10400435.2003.10131898

11. Shirogane S, Toyama S, Hoshino M, Takashima A, Tanaka T. Quantitative Measurement of the Pressure and Shear Stress Acting on the Body of a Wheelchair User Using a Wearable Sheet-Type Sensor: A Preliminary Study. *Int J Environ Res Public Health*. 2022;19(20). doi:10.3390/ijerph192013579

12. Chung CS, Grindle GG, Brown JD, et al. Anthropomorphic model rigid loading indenter with embedded sensor development for wheelchair cushion standard testing. *Med Biol Eng Comput*. 2023;61(2):329-340. doi:10.1007/s11517-022-02720-y

13. Karg P, Brienza D, Delazio A, Terhorst L, Smith C. Effects of simulated aging on cushion performance measured using standardized laboratory test methods. *Assist Technol*. Published online 2022. doi:10.1080/10400435.2021.2024626

14. Gefen A, Brienza DM, Cuddigan J, Haesler E, Kottner J. Our contemporary understanding of the aetiology of pressure ulcers/pressure injuries. *Int Wound J*. 2022;19(3):692-704. doi:10.1111/iwj.13667

Appendices

Appendix A.

RERC Cushion decoder for cushions manufactured by Permobil

Cushion	ID in Figures
Comfort Embrace	AZ
Comfort Express Comfort Foam	D
Comfort M2	AG
Comfort M2 with Glidewear	AH
Comfort Saddle	AF
ROHO Hybrid Select	L
ROHO MOSAIC	AA
ROHO QUADTRO SELECT High Profile	AV
ROHO Single Compartment Low Profile	BA
ROHO Single Compartment High Profile	AT

Setup Procedure for testing completed by RERC:

ROHO Hybrid Select: Inflated to atmospheric pressure; locked with test load applied

ROHO MOSAIC: Inflated to 0.5” clearance under test load

ROHO QUADTRO SELECT High Profile: Inflated to 0.5” clearance under test load; locked with test load applied

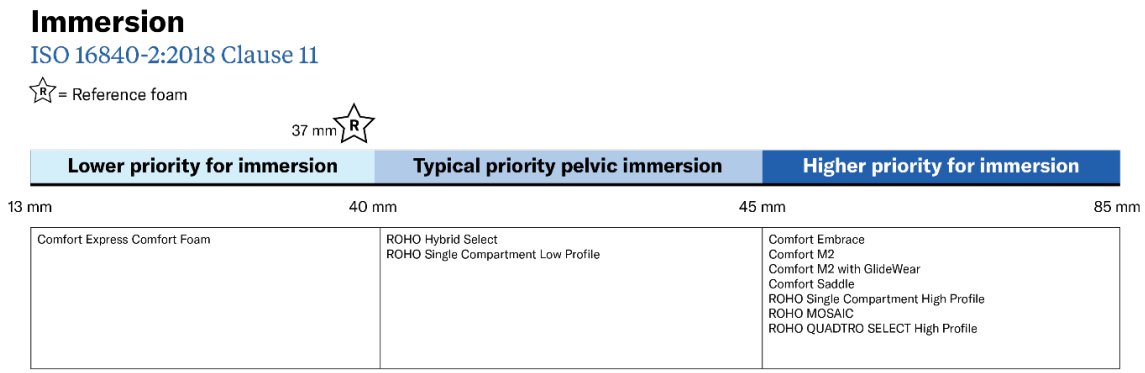
ROHO Single Compartment High Profile: Inflated to 0.5” clearance under test load

ROHO Single Compartment Low Profile: Inflated to 0.5” clearance under test load

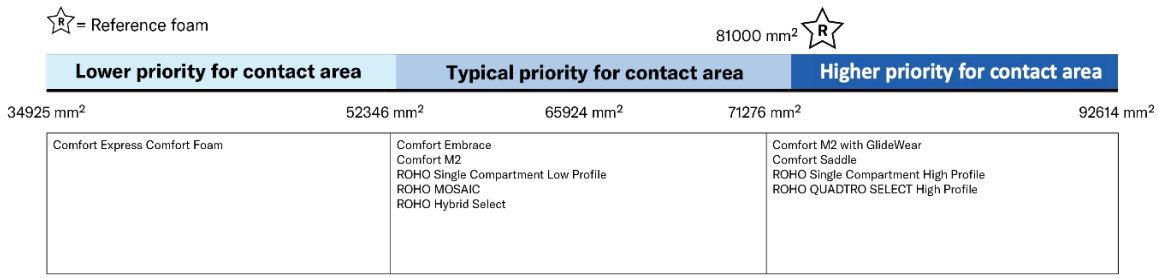
Appendix B. Detailed results for primary performance metrics.

In all results presented below, the reference foam cushion K is presented by R

B1.



B2.



B3.1

Off-loading

ISO 16840-12:2021 small indenter ((Non-IT pressure/total pressure)*100%)

= Reference foam

84% R

Lower priority for off-loading IT	Typical priority off-loading IT	Higher priority for off-loading IT
77% – 84%	84% – 88%	88% – 100%
ROHO MOSAIC Comfort Express Comfort Foam	Comfort Embrace Comfort M2 Comfort M2 with GlideWear ROHO Hybrid Select ROHO QUADTRO SELECT High Profile	ROHO Single Compartment Low Profile ROHO Single Compartment High Profile Comfort Saddle

B3.2

Off-loading

ISO 16840-12:2021 large indenter ((Non-IT pressure/total pressure)*100%)

= Reference foam

83% R

Lower priority for off-loading IT	Typical priority for off-loading IT	Higher priority for off-loading IT
75% – 84%	84% – 88%	88% – 100%
ROHO MOSAIC Comfort Express Comfort Foam	Comfort Embrace Comfort M2 Comfort M2 with GlideWear ROHO Hybrid Select ROHO QUADTRO SELECT High Profile	ROHO Single Compartment Low Profile ROHO Single Compartment High Profile Comfort Saddle

B4.

Lateral stability

ISO 16840-13:2021 Average tilt angle after 60 sec.

R = Reference foam

6.6° R

Lower priority for lateral stability	Typical priority for lateral stability	Higher priority for lateral stability
7.5°	5.9° 4.6°	4.2° 2.7°
ROHO Single Compartment High Profile ROHO Single Compartment Low Profile ROHO MOSAIC	Comfort Embrace Comfort M2 Comfort M2 with GlideWear Comfort Saddle ROHO QUADTRO SELECT High Profile	Comfort Express Comfort Foam ROHO Hybrid Select

B5.

Horizontal stiffness

ISO 16840-2:2018 Annex C Peak force

R = Reference foam

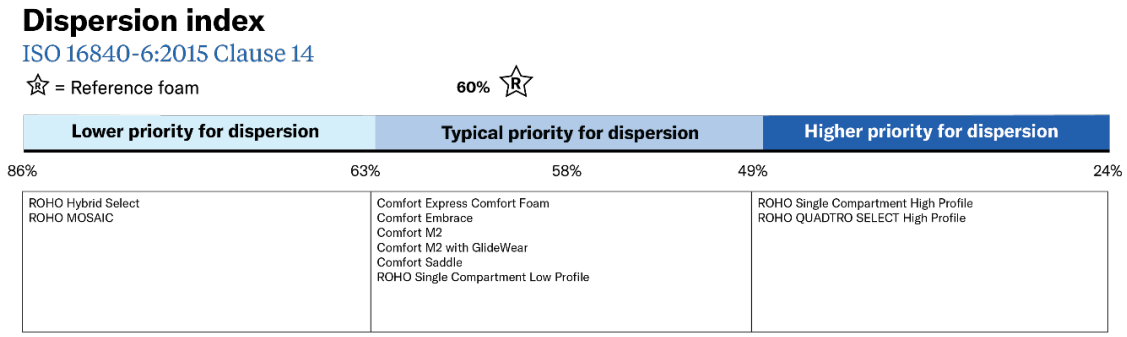
135 N R

Lower priority for horizontal stiffness	Typical priority for horizontal stiffness	Higher priority for horizontal stiffness
63 N	126 N 138 N	161 N 369 N
Comfort M2 with GlideWear ROHO Single Compartment High Profile ROHO Single Compartment Low Profile ROHO QUADTRO SELECT High Profile	ROHO Hybrid Select ROHO MOSAIC Comfort M2	Comfort Embrace Comfort Express Comfort Foam Comfort Saddle

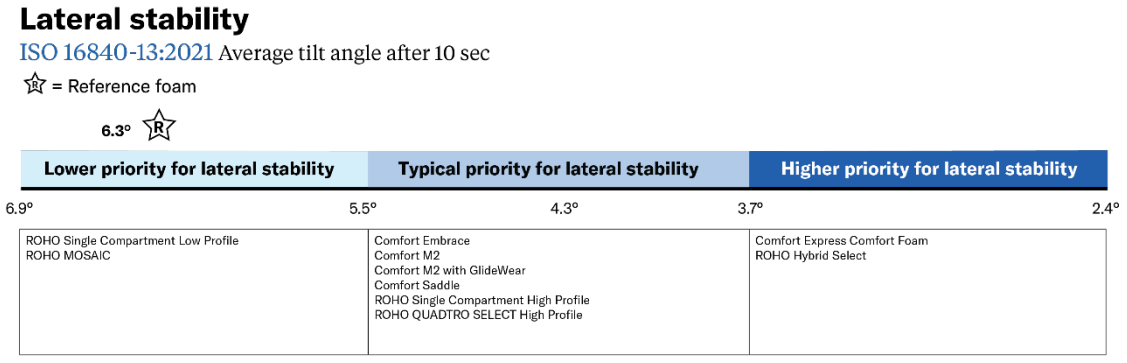
Appendix C. Detailed results for secondary performance metrics

In all results presented below, the reference foam cushion K is presented by 

C1.



C2.



C3.

Horizontal stiffness

ISO 16840-2:2018 Annex C Final force

= Reference foam

96 N

Lower priority for horizontal stiffness	Typical priority for horizontal stiffness	Higher priority for horizontal stiffness
42 N	82 N / 98 N	118 N / 254 N
Comfort M2 with GlideWear ROHO Single Compartment Low Profile ROHO QUADTRO SELECT High Profile	Comfort M2 ROHO Single Compartment High Profile ROHO Hybrid Select ROHO MOSAIC	Comfort Embrace Comfort Express Comfort Foam Comfort Saddle

C4.

Impact damping

ISO 16840-2:2018 Clause 9 Initial impact acceleration

= Reference foam

19.1 m/s²

Lower priority for impact damping	Typical priority for impact damping	Higher priority for impact damping
54.8 m/s²	32.4 m/s² / 28.2 m/s²	23.6 m/s² / 19.1 m/s²
ROHO MOSAIC	Comfort M2 with GlideWear ROHO Single Compartment High Profile ROHO Single Compartment Low profile ROHO Hybrid Select ROHO QUADTRO SELECT High Profile	Comfort Embrace Comfort Express Comfort Foam Comfort M2 Comfort Saddle

C5.

Impact damping

ISO 16840-2:2018 Clause 9 Impact ratio

= Reference foam

30%

Lower priority for impact damping	Typical priority for impact damping	Higher priority for impact damping
57% – 46%	37% – 31%	11%
ROHO MOSAIC	Comfort Express Comfort Foam Comfort Saddle ROHO Single Compartment High Profile ROHO Single Compartment Low Profile ROHO Hybrid Select ROHO QUADTRO SELECT High Profile	Comfort Embrace Comfort M2 Comfort M2 with GlideWear

C6.1

Hysteresis

ISO 16840-2:2018 Clause 14 250 N

= Reference foam

15 N

Lower priority for hysteresis	Typical priority for hysteresis	Higher priority for hysteresis
48 N – 16 N	11 N – 9 N	3 N
Comfort Express Comfort Foam ROHO Single Compartment High Profile ROHO Single Compartment Low Profile ROHO MOSAIC ROHO QUADTRO SELECT High Profile	Comfort Embrace Comfort Saddle	Comfort M2 Comfort M2 with GlideWear ROHO Hybrid Select

C6.2

Hysteresis

ISO 16840-2:2018 Clause 14 500 N

☆ = Reference foam

17 N ☆R

Lower priority for hysteresis	Typical priority for hysteresis	Higher priority for hysteresis
27 N – 12 N	8 N – 5 N	1 N
Comfort Express Comfort Foam ROHO Single Compartment High Profile ROHO MOSAIC ROHO QUADTRO SELECT High Profile	Comfort M2 Comfort M2 with GlideWear Comfort Saddle	Comfort Embrace ROHO Hybrid Select ROHO Single Compartment Low Profile

C7.

10% force deflection

ISO 16840-6:2015 Clause 20 Average force

☆ = Reference foam

146 N ☆R

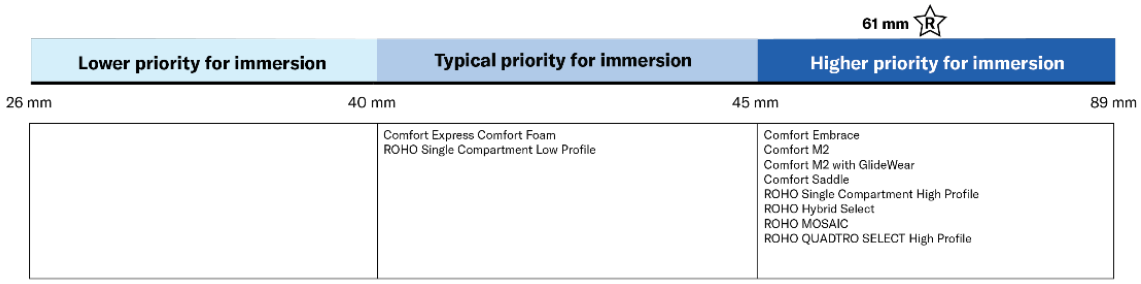
Lower priority for force deflection	Typical priority for force deflection	Higher priority for force deflection
383 N – 104 N	40 N – 22 N	9 N
Comfort Express Comfort Foam	ROHO Single Compartment High Profile ROHO Single Compartment Low Profile ROHO QUADTRO SELECT High Profile	Comfort Embrace Comfort M2 Comfort M2 with GlideWear Comfort Saddle ROHO Hybrid Select ROHO MOSAIC

C8.1

Envelopment – immersion

ISO 16840-12:2021 nominal load – small indenter

☆ = Reference foam



C8.2

Envelopment – immersion

ISO 16840-12:2021 nominal load – small indenter

☆ = Reference foam