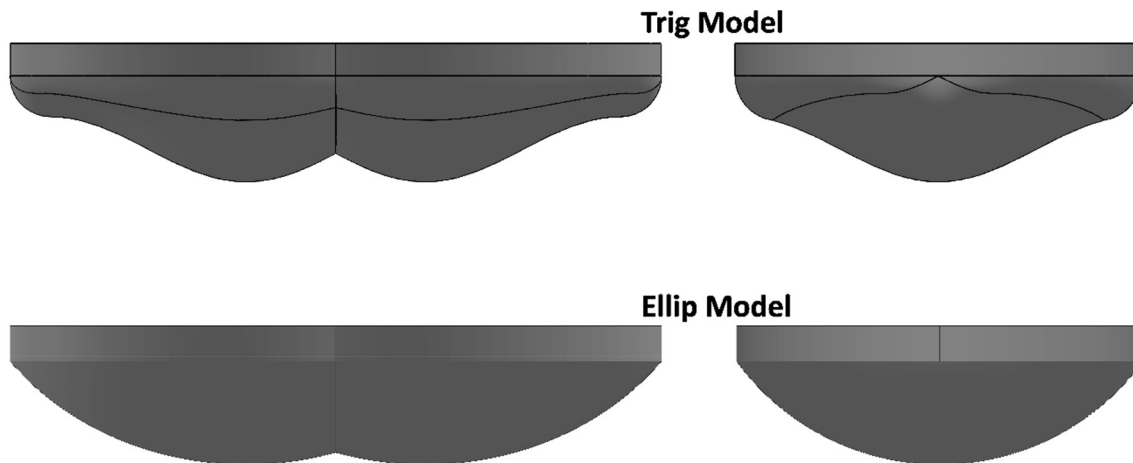


Procedure to categorize wheelchair cushion performance using compliant buttock models

Supplement for dataset

Buttock Models



Substructure indicating locations of internal pressure sensors	Surface sensors
<p>Internal Pressure Sensors</p>	<p>anterior</p> <p>11 cm</p> <p>4 cm</p> <p>6 cm</p>

Surface pressure redistribution measurement and analysis

The pressure redistribution parameter uses surface sensors to calculate the percentage of surface pressures at locations under the 3 rigid protuberances (SumBony) relative to the sum of all surface sensors (TotSufSum). Referencing **Error! Reference source not found.**,

$$\%Bony = \frac{\text{SumBony}}{\text{TotSufSum}} = \frac{\text{Sum of values at sensors 1, 2, 7, 8, 9, 10}}{\text{Sum of values 1 - 12}} \quad (1)$$

An enviable cushion should redistribute pressures away from high risk areas under bony prominences. Consider sitting on a rigid or low compliance surface. The majority of pressures will be borne by bony aspects rather than being redistributed over the buttocks surface, representing poor pressure redistribution.

The mean and standard deviation of the %Bony parameter was calculated using 6 repeated trials on each cushion and at each load. Analysis is based upon the 95th percentile confidence interval (CI):

$$CI = \mu \pm \sigma / \sqrt{n} \quad (2)$$

where μ = sample mean; σ = sample standard deviation, and n = number of trials

Combining the results of the two loading profiles purposely impacts the analysis because the CIs will be larger due to increased variance. A cushion which supports the two loads in a similar manner will benefit by a resulting smaller CI. This is fair, because cushions that support persons of different mass in a similar manner reflect an advantageous performance.

Thresholds were defined using a combination of a theoretical premise and empirical results. The redistribution parameter is a criterion-referenced value using 50% for the ellip model, thus establishing the upper threshold that 50% of the surface pressures are under ‘bony’ areas, which reflects a pressure redistribution away from the high-risk areas. The trig model uses a threshold of 55%, reflecting a theoretical premise that its design with a more prominent curvature and peaked shape results in greater loading under the medial protuberance. In addition, empirical testing of a 3” block of high resiliency foam with a 44 ILD produced %Bony values of 0.5 using the ellip model and 0.56 on the trig model.

The criteria are defensible based upon the benefit of redistributing pressures away from the underlying bony protuberances of the models. This parameter will reflect the performance of off-loading cushions which redirect pressures away from at-risk sites as well as enveloping cushions which seek to equalize pressures across the buttocks. As such, greater redistribution reflects a more desirable performance category regardless of the approach adopted by the cushion.

The redistribution parameter is used to create a trichotomous classification, being divided by whether the 95th % CI falls below, around, or above the respective threshold, using high, moderate and low categories (Table 1).

Table 1 Pressure redistribution classification definitions

Designation	Elliptical criterion	Trigonometric criterion	Description
High redistribution	< 0.5	<0.55	the CI falls below criterion
Moderate redistribution	~ 0.5	~ 0.55	the CI includes criterion
Low redistribution	> 0.5	>0.55	the CI lies above criterion

Internal pressure measurement and analysis using Equivalence Testing

Internal pressures offer an opportunity to represent the loading that occurs at the tips of bony prominences. Longstanding research suggests that soft tissue stresses are the greatest at the interface between bone and soft tissues [26, 42-44].

The parameter of interest is the sum of the three internal sensors (SumInt) within the model substructure. This evaluation uses a reference material to determine performance. An advantageous cushion will have lower SumInt values than the reference material. Reference materials consist of flat block foam with different references used for Skin Protection and General Use designations. When evaluating Skin Protection cushions, a block of 3” thick high resiliency (HR) foam is used with a nominal IFD value near 45 lb and a density exceeding 2.5 lb/in³. General Use cushions are evaluated against a 2” HR45 HR foam block. This creates a more stringent standard for Skin Protection cushions compared to General Use cushions, reflecting the intent of the HCPCS classifications.

Equivalence tests assess when device performance differs by more than a practically relevant or meaningful amount. Its analysis is often more appropriate than inferring a lack of a difference when assessed by traditional statistical means [45]. Operationally, equivalence tests are a two-sided evaluation of differences using confidence intervals. A formal equivalence test is not being proposed here, rather its underlying premise and computational approach is being adopted to compare a Reference material to Test cushions.

Test Mean/Reference Mean is the parameter of interest, including the CI of this ratio. Its relationship to pre-defined equivalence limits are used to assign three categories of pressure magnitude performance. The lower equivalence limit is set equal to 0.9 and the upper equivalence limit = 1.1 which define a noticeable or meaningful difference at 10%. Lower magnitude of pressures exhibited by the Test cushion indicates a higher level of performance (Table 2).

Table 2 Pressure magnitude classification definitions

$CI_p \leq LEL$	<i>Superior.</i> The entire CI of the ratio (ρ) of the mean of the test cushion to the mean of the reference material is less than or equal to the lower equivalence limit (LEL).
$CI_p \geq UEL$	<i>Inferior.</i> The entire CI of the ratio (ρ) of the mean of the test cushion to the mean of the reference material is greater than or equal to the upper equivalence limit (UEL).
Low $CI_p > LEL$ or High $CI_p < UEL$	<i>Comparable.</i> The CI of the ratio (ρ) of the mean of the test cushion to the mean of the reference material crosses either the LEL or UEL or lies fully between them.