Medicare K0009 Manual Wheelchair Manual

January 28, 2013

Prepared By:

NCART
National Coalition for Assistive and Rehab Technology

AND

itf Clinician Task Force

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Overview of Information Provided for
Medicare K0009 Classification Initiative

January 28, 2013

To assist in the K0009 Review Project, the National Coalition for Assistive and Rehab Technology (NCART) and the Clinician Task Force (CTF) have prepared this **Medicare K0009 MWC Manual** and a supplemental **Evidence Binder.**

The purpose of these documents is to provide the CMS and PDAC staff with technological, scientific and clinical information regarding four categories of complex rehab technology (CRT) products that should remain coded as HCPCS code K0009 or be classified under new HCPCS codes established through a process that includes stakeholder input. The materials focus only on CRT items presently classified within K0009 and exclude non-CRT items. The CRT product categories within K0009 are:

1. Positioning Tilt In Space (<45°) Manual Wheelchairs
2. Made To Measure Manual Wheelchairs
3. Bariatric Manual Wheelchairs with Special Features
4. Standing Manual Wheelchairs

This Medicare K0009 MWC Manual is organized in specific sections as outlined in the Table of Contents. The Introduction section includes letters from prominent researchers in the area of CRT and outcomes research. There are additional sections for each of the four product categories that include details regarding: the technology; technological characteristics or features that distinguish them from other devices; definitions to assist in understanding each technology's capacity; and details as to when each device was introduced to the market, retail pricing and utilization. Clinical indicators and case examples[1] that demonstrate the population of people who benefit from the technology are also provided.

In developing this information, a review of over 120 peer reviewed articles related to CRT manual wheelchairs was completed. Relevant articles were identified and an Evidence Summary is provided in each product category section. Limited copies of the relevant original articles are provided in a separate Evidence Binder.

The NCART/CTF goal is to provide the CMS and PDAC staff with information that will assist in determining code-verification of the above products within the K0009 code and general indications for coverage of these technologies. The information is NOT intended to provide the comprehensive information necessary to develop definitions or characteristics for new HCPCS codes or to inform modifications to the Manual Wheelchair LCD. That extensive information will require additional time to develop. For instance, when manufacturers submitted data for the various spreadsheets, they did not always represent the data in the same manner. To convert and standardize the data for consistency would take a considerable amount of time. That level of detail would most likely be important in assisting to establish code requirements or characteristics.

[1] Actual clients were the basis for the case examples. In certain instances, additional details were added to help clarify the need for the specific technology.

The current HCPCS codes do not allow for appropriate recognition of complex rehab technology and this forces a number of items to be billed using miscellaneous codes, specifically K0009 and K0108. In addition, unique HCPCS codes that are defined as "any type" or have vague definitions are particularly challenging for CRT items. HCPCS codes that group dissimilar technologies, or comingle DME and CRT items, and/or group products with a variable range of features, function, and clinical applications are specifically problematic.

We are not advocating that unique codes are required for each individual product. Instead, we believe that as we move forward thoughtful consideration of the technology and further collaboration will allow for adequate grouping of homogeneous products. We suggest that unique HCPCS codes are required where technological distinction, differences in clinical application, or patient population exists. Establishing a unique code that is well defined, including code definitions and characteristics, allows various payers to develop appropriate coverage polices and payments to reflect the goals of their program and the people they serve.

We support the consideration of evidence in policy development. However we point out that there is no one "scientific method" that can account for the influence of experience, intuition and creativity in clinical judgment.[2] It is important to recognize the challenges and barriers that exist in designing and conducting rigorous scientific studies involving complex rehab technology. Research designs appropriate for evaluating pharmacologic interventions have to be considerably amended for assessing the outcomes of complex rehabilitation technology.

Lack of adequate HCPCS codes to represent heterogeneous CRT products remains a significant barrier to conducting comparative effectiveness research. Findings from this type of research are extremely useful in identifying who benefits from the use of technology grouped within a HCPCS code. Under the current code set product-to-product comparison even within the same HCPCS code would result in very different outcomes for people with disabilities. The grouping of dissimilar technology into one code challenges the development of meaningful and comprehensive Local Coverage Determinations for CRT and results in inequitable payment for the items within that same code. The end result is a major negative impact on access.

In closing, based on the information and materials presented, we recommend the following:

1. The four categories of CRT products should remain coded as HCPCS code K0009 or be classified under new HCPCS codes established through a process that includes stakeholder input.
2. The four categories presented should be formally classified as complex rehab technology so they are subject to the appropriate coverage and quality standards.

We look forward to additional discussions in this area and stand ready to assist CMS and its contractors on this project and in other matters related to the coverage, coding, and payment of CRT.

[2] Foundations of Clinical Research-Applications to Practice- Third Edition

NCART

National Coalition for Assistive and Rehab Technology

AND

Clinician Task Force

Materials for this binder were prepared collaboratively by NCART (National Coalition for Assistive and Rehab Technology) and the Clinician Task Force under the leadership of Rita Hostak and Laura Cohen. Please contact Rita or Laura directly with any questions.

Rita Hostak
Chair, NCART Regulatory Committee
NCART MWC Coding Committee
VP Government Relations, Sunrise Medical
Phone / 704-846-4096
Email / rita.hostak@sunmed.com

Laura Cohen PT, PhD, ATP/SMS
Executive Director, Clinician Task Force
Principal, Rehabilitation & Technology Consultants, LLC
Phone / 404-370-6172
Email / laura@rehabtechconsultants.com

CTF Member List [1]

Executive Director

Laura Cohen, PhD, PT, ATP/SMS
Principal
Rehabilitation & Technology Consultants, LLC
Arlington, VA
Laura@rehabtechconsultants.com
RESNA Member, RESNA Fellow, APTA Member, Friend of NRRTS, NCART Board

Executive Board

Barbara Crume, PT, ATP
Seating and Mobility Clinic Manager
CarePartners Health Services
Asheville, NC
Bcrume@CarePartners.org
APTA Member, Friend of NRRTS

Allison Fracchia, PT, ATP/SMS
Clinical Coordinator Seating and Wheeled Mobility Clinic
Methodist Rehabilitation
Jackson, MS
allisonfracchia@mmrcrehab.org
RESNA member, APTA member, Friend of NRRTS

Jill Monger, PT, MS, ATP
Coordinator Seating and Mobility Clinic
Medical University of South Carolina
Charleston, SC
carterjm@musc.edu
APTA Member, RESNA Member

Jill Sparacio, OTR/L, ATP/SMS, ABDA
Sparacio Consulting Services
Downers Grove, IL
Otspar@aol.com
AOTA Member

Task Force Members

Michael Babinec, OTR/L, ABDA, ATP
Global Product Manager
The Invacare Corp.
Elyria, Ohio
mbabinec@invacare.com
RESNA Member, AOTA Member, Friend of NRRTS

[1] Italicized names connote members involved in one or more of the following activities for the purpose of this project: reviewing literature, developing case examples, and/or developing, reviewing, or editing draft documents.

Theresa F. Berner, MOT, OTR/L, ATP
Rehab Team Leader, Assistive Technology Center
The Ohio State University Medical Center
Columbus, OH
Theresa.Berner@osumc.edu
RESNA Member, AOTA Member

Erin Bishchofberger, PT, DPT, ATP
Physical Therapist, Seating and Wheeled Mobility Clinic
Methodist Rehabilitation
Jackson, MS
ebishofberger@mmrcrehab.org

Cathy Carver, PT, ATP/SMS
UAB/Spain Rehab Center
Birmingham, AL
ccarver@uabmc.edu
RESNA Member, APTA Member

Susan Christie, PT, ATP
Advanced Clinician, Assistive Technology Center
Bryn Mawr Rehab Hospital
Malvern, PA
christies@MLHS.org
RESNA Member

Elizabeth Cole, MSPT, ATP
Director of Clinical Rehab Services
US Rehab
Waterloo, IA
Elizabeth.Cole@usrehab.com
RESNA Member, Friend of NRRTS

Barbara Crane, PhD, PT, ATP/SMS
Associate Professor, Physical Therapy
University of Hartford
West Hartford, CT
barb.crane@hartford.edu
APTA Member

Brad Dicianno, MD
Associate Professor
University of Pittsburgh
Pittsburgh, PA
dicianno@pitt.edu
AAP, RESNA

Gerry Dickerson, ATP, CRTS
VP of Rehab Technology
MedStar Surgical, Inc.
College Point, NY
gdcrts@aol.com
NRRTS BOD- VP, RESNA Fellow, RESNA BOD, NCART BOD, NYMEP Member

Linda Elsaesser, PT, ATP President,
Elsaesser Consulting, Inc.
Saylorsburg, PA
elsaesserconsulting@gmail.com
RESNA Member, APTA Member

Jan Furumasu, PT ATP
Physical Therapy Instructor
Rancho Los Amigos National Rehabilitation Center
Downey CA
jfurumasu@dhs.lacounty.gov
RESNA Member

Tricia Garven, MPT, ATP Clinical
Applications Manager The
Roho Group
Pasco, WA
TriciaG@therohogroup.com
RESNA Member, APTA Member

Theresa L. Gregorio-Torres, MA, OTR, ATP
Seating & Mobility Specialist
TIRR/Memorial Hermann Hospital and Univ. of Texas, M.D. Anderson Cancer Center
Houston, TX
vttg@entouch.net
AOTA member, AOTA member for Consortium of Spinal Cord Medicine, TOTA

Tamara Kittelson-Aldred, MS, OTR/L, ATP
Occupational Therapist
Community Medical Center
Missoula, MT 59801
tamaralka@gmail.com
RESNA member, AOTA member, Friend of NRRTS

David Kreutz, PT, ATP
Physical Therapist, Seating Clinic Coordinator
Shepherd Center
Atlanta, GA
David_Kreutz@shepherd.org

Eva K. Ma, OTR, ATP
Early Childhood Special Educational Program of Multnomah Educational Services District
Portland, OR
EvaMa1616@yahoo.com

Simon Margolis, ATP/SMS
Executive Director
National Registry of Rehabilitation Technology Suppliers (NRRTS)
Maple Grove, MN
smargolis@nrrts.org
RESNA Fellow, NRRTS Honorary Fellow

Chris Maurer, MPT, ATP
Physical Therapist, Seating Clinic, Clinical Researcher
Shepherd Center
Atlanta, GA
Chris_Maurer@shepherd.org
APTA Member, RESNA Member

Jean L. Minkel, PT, ATP
Sr. Vice President of Rehab Services
Independence Care System
New York, NY
jminkel@aol.com
RESNA Member, RESNA Fellow, APTA Member, Neuro Section Member

Erin Michael, PT, DPT, ATP
Clinic Equipment Coordinator
The International Center for Spinal Cord Injury
Kennedy Krieger Institute
Baltimore, MD
michaele@kennedykrieger.org

Mary O'Connell, PT, ATP/SMS
Community Medical Center
OP Equipment Clinic
Missoula, MT
themarys2@optimum.net

Ginny Paleg, PT, MS, DScPT
Physical Therapist
Maryland Insurance Commission
Silver Spring, MD
ginny@paleg.com
APTA Member, AACPDM member

Jessica Presperin Pedersen, MBA, OTR/L, ATP
Owner
Presperin Pederson and Associates and CREATE
Frnklin Park, IL
jjpedersen@comcast.net
AOTA Member, RESNA Member, Friend of NRRTS, IOTA Member, RESNA Fellow

Cindi Petito, OTR/L, ATP, CAPS
Owner, Seating Solutions, Inc.
Orange Park, FL
Cindi@SeatingSolutionsInc.com
AOTA Member, FOTA Member, RESNA Member

Penny J. Powers, PT, MS, ATP
Pi Beta Phi Rehab Institute
Vanderbilt Medical Center
Nashville, TN
Penny.powers@vanderbilt.edu
APTA Member, RESNA Member, TNPTA

Tina Roesler, PT, MS, ABDA
TiLITE
Director of Education and International Sales
Springfield, VA
troesler@tilite.com
RESNA Member, APTA Member, ABDA

Lauren E. Rosen, PT, MPT, MSMS, ATP/SMS
Program Coordinator
St. Joseph's Hospital
Tampa, Florida 33607
PTLauren@aol.com
RESNA BOD, APTA, Friend of NRRTS, AACPDM

Mary Shea, MA, OTR/L, ATP
Clinical Manager, Wheelchair Services
Kessler Institute for Rehabilitation
West Orange, NJ
mshea@kessler-rehab.com
RESNA Member, AOTA Member, NYSOTA Member

"Jodie" Kitty J. Stogner, PT, ATP/SMS
Rehab Product Specialist
Pride Mobility/Quantum Rehab
Jackson, MS
seatsolutionsllc@gmail.com
RESNA member, APTA member, APTA Section on Geriatrics

Christine Syfu Beecham, OTR/L ATP
Seating Clinic
Banner Good Samaritan Rehab Institute
Phoenix, AZ
Christine.beecham@bannerhealth.com

Patricia E. Tully, OTR, ATP
WC Seating and Mobility Specialist
TIRR Memorial Hermann
Houston, TX
Patricia.tully@memorialhermann.org

Susan Ventura, PT, PhD, ATP/
SMS Associate Clinical Professor
Northeastern University
Boston, MA
s.ventura@neu.edu
APTA member, RESNA member

Ginger Walls, PT, MS, NCS, ATP/SMS
Regional Director
Medstar NRH Rehabilitation Network
Washington, DC
Virginia.st.walls@medstar.net
APTA member, RESNA member

Ashley Williams, PT, DPT
Pediatric Physical Therapist
Therapeutic Mobilities, LLC
Florence, SC
Willlillsc22@yaho.com
APTA member

KEY

AOTA- American Occupational Therapy Association

APTA- American Physical Therapy Association

BMES- Biomedical Engineering Society

IEEE-EMBS- Institute of Electrical and Electronics Engineers - Engineering in Medicine and Biology Society

NAPT- National Association for Pupil Transportation

NCART- National Coalition for Assistive and Rehab Technology

NRRTS- National Registry of Rehabilitation Technology Suppliers

NYMEP- New York Medical Equipment Providers

MAMES- Mississippi Association of Medical Equipment Suppliers

RESNA- Rehabilitation Engineering and Assistive Technology Society of North America

January 21, 2013

Susan Miller, MD
U.S. Department of Health & Human Services
Centers for Medicare Services
OA/OCSQ/CAG/DID
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. Miller:

I am writing in respect to the review being conducted by CMS of coding and coverage policies for several specialized manual wheelchairs. My hope is that CMS will adopt the same encompassing perspective it previously took in assessing wheeled mobility devices and powered wheelchairs. That perspective incorporated the available research evidence, analytic reviews by knowledgeable clinicians, and the reports of multiple users. The alternative of depending solely on formal research regarding the devices' effectiveness, and at the same time, emphasizing reliance on ostensibly "conclusive" studies, will prejudice the review and obscure appreciation of the value of these devices for facilitating their users' health and performance of mobility-related daily activities.

My comments stem from two personal vantages. The first is my pre-retirement role at NIH where I served as founding director of the National Center for Medical Rehabilitation Research, the focus for such research at the NIH. Assistive technology research was a priority for the Center during those early years. That experience formed the basis of my subsequent involvement in the area as an active researcher, a role that continues to this day.

My reservation about basing this policy determination almost entirely on available research evidence stems from a widely acknowledged sense of the shortcomings of contemporary assistive technology research. Those deficiencies and the constraints they reflect were made clear to CMS during its earlier reviews of mobility assistive devices. Many are attributable to the complexity of device usage resulting from the diversity of the user populations and their relatively low prevalence, the variety of environmental situations in which devices are used, the numerous different benefits they potentially afford, the multiplicity of adaptations and modifications that are made in them during the process of service provision, and the varied approaches that are taken to training new users. Above all is the well-documented paucity of funding available for assistive technology outcomes research. In aggregate, these deficiencies assure the existence of very few mobility device outcome studies based on the preferred randomized controlled design. Insisting on that level of evidence for these devices, indeed, for most complex rehabilitation technologies, is tantamount to preordaining that they will be denied authorization. Therefore, it is critical that CMS utilize a balance approach to evaluation that considers other types of evidence such that based on clinical expertise and the values of users and their caregivers. This critique is not to suggest an absence of research findings regarding the benefits of the mobility devices under scrutiny. Such research indeed exists, consisting predominately of uncontrolled studies that are retrospective in orientation. While no one study can be considered to be conclusive, the tenor of the aggregate findings, whether positive or negative, certainly merits a role shaping CMS's final determination. Combining that evidence with the critical reviews of informed professionals and surveys of users' experience will constitute a balanced assessment allowing a prudent decision to be reached about each of the devices under review.

Thank you for considering my views.

Sincerely yours,

Marcus J. Fuhrer, Ph.D.
Scientist Emeritus
National Institutes of Health

cc: Stacey V. Brennan, MD, Medical Director, Region B
Paul J. Hughes, MD, Medical Director, Region A
Robert D. Hoover, Jr., MD, MPH, FACP, Medical Director, Region C
Richard W. Whitten, MD, MBA, FACP, Medical Director, Region D

Georgia Tech | School of Applied Physiology
College of Sciences

Susan Miller, MD
U.S. Department of Health & Human Services
Centers for Medicare Services
OA/OCSQ/CAG/DID
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. Miller:

I have been asked to write this letter to express my opinions about issues related to research and public policy in assistive technology, and specifically wheeled mobility and seating equipment. I welcome this opportunity and hope that my thoughts, in combination with those from other researchers, can spur a healthy dialog about studying the impacts of assistive technology (AT) in a manner useful to CMS.

As you are well aware, the design of a research project includes the objectives to minimize bias and maximize generalization. Because these objectives can be in conflict, researchers must make a series of compromises in an attempt to judiciously balance them. The unique characteristics of wheelchair users and their use of technology require researchers to adopt methodologies that reflect the idiosyncrasies of the constructs and cohorts under study. Furthermore, research designs are complicated by the need to study both functional and medical outcomes.

Because AT reflects a functional construct rather than a medical one, defining inclusion and exclusion criteria based upon diagnosis reduces validity. The functional differences within diagnoses reduce homogeneity of the cohort and the equipment being used, and obfuscate the focus on the device. The International Classification of Function (ICF) offers a better and more valid option to characterize users of technology. When researchers are forced to limit inclusion to a specific diagnosis, it lessens the ability of CMS to utilize results to inform policy.

The functional nature of AT also impacts the study of its outcomes. AT is used to support the health, activity and participation of persons with disabilities- which are also tenets of the ICF. It is naïve to believe that full time wheelchair users use wheelchairs purely for medical purposes. Wheelchairs offer mobility assistance and postural support to increase function and independence as well as preventing medical complications. Full time wheelchair users require mobility assistance in all aspects of their lives, and research must acknowledge this. In fact, the tenets of ethics (and Federal Law) require us to allow research participants to use AT devices within the course of their daily lives. Can you imagine the response of an IRB Committee if we told subjects that they can use wheelchairs only during 'mobility-related activities of daily living', but not to attend church services or travel to a grocery store?

From the perspective of internal validity, one common approach to managing bias is blinding. Blinding is only appropriate when it does not impact the operation or function of the intervention. This is simply not possible for studies of wheeled mobility and seating devices. Even if you could 'visually blind' a device without impacting its function, you cannot 'functionally' or 'sensory' blind it and, therefore, users could easily tell the difference while using the device. For example, the differences between foam and air cushions are obvious while sitting, transferring and managing the cushion, regardless of whether you can see it.

Similarly, when measuring outcomes, evaluators cannot be blinded to the intervention, because outcomes have to be measured while the person is using the device. Potential bias can and should be managed by objective and independent assessment. A treating physician or therapist who prescribed the intervention simply cannot be involved in judging that intervention. Moreover, valid and objective measurements must offer requisite reliability and validity to manage both the internal and external validity requirements of research. Therefore, managing bias is possible, but blinding is not the means to do so.

Another challenge in studying wheelchairs and seating interventions concerns timelines for between subject and within subject research methodologies. Outcomes of using AT have a long timeframe from both medical and functional perspectives. Because AT is typically not prescribed to treat a condition, medical outcomes relate to prevention. Clearly, prevention is harder to study than treatment, and requires longer timeframes. Between subject designs are hindered by the wide variety of people using the same type of equipment and how they use it. With respect to community-living wheelchair users, measurement of functional and medical outcomes are confounded by many factors such as living environment, attendant care, access to personal transportation, and employment and economic status. Researchers face a herculean challenge if they try to match subjects across all these factors given the relatively low incidence of wheelchair use. Within subject designs become a more judicious option, but also present a challenge because, to be valid, the subject cohort must remain functionally and medically stable throughout the study. As examples, this latter requirement obviates the use of within study designs for studying pediatric wheelchairs or seating systems for adults with progressive conditions.

I often hear people bemoan the fact that research is not useful to defining HCPCS Coding. In my opinion, device codes are really an artificial construct with respect to wheelchairs and seating. For one, codes are US-centric, so have no meaning outside of the US. More importantly, however, devices within a single code typically do not have the requisite homogeneity to permit valid comparisons. Coding has been, in large part, based upon simple physical characteristics (i.e., weight of a wheelchair; presence of a 1" positioning feature in a wheelchair cushion), rather than performance. I cannot believe that CMS (or anybody) really believes that the mass of an unoccupied manual wheelchair is singularly predictive of ease of propulsion. In my opinion, manufactures and CMS share the responsibility for this situation, and, therefore, should participate in rectifying it. We need to code products based upon performance so policy-makers and researchers can study devices. Currently, researchers attempt to group devices independent of HCPCS coding. This, in turn, hinders CMS's ability to use research to inform coding and coverage policy.

In my opinion, the best approach for designing studies that are of interest to CMS or other policy-makers is for these entities to be involved in designing the research studies. As stakeholders in the research, policy-makers would benefit tremendously, as would researchers and, by extension, the beneficiaries. As mentioned above, designing research entails making a series of compromises, and CMS should not shy away from this activity if it is interested in utilizing research results to develop policy.

In summary, I believe that CMS can do a few small, yet significant things can be done to improve research on wheeled mobility and seating devices:

- Promote the use the ICF to base subject inclusion rather than diagnosis.
- Acknowledge the fact that certain research designs to not apply to interventions that target both functional and medical outcomes.
- Devise a system to engage researchers during the planning stage to insure researchers meet the needs of CMS as a stakeholder.
- Support research into categorizing products by performance.

I am always willing to discuss this issue with you or your colleagues, so if you require additional information, please feel free to contact me

Yours very truly,

Stephen Sprigle, PhD, PT
Professor and Director
Rehabilitation Engineering and Applied Research Lab
sprigle@gatech.edu

CC: Stacey V. Brennan, MD, Medical Director, Region B
Paul J. Hughes, MD, Medical Director, Region A
Robert D. Hoover, Jr., MD, MPH, FACP, Medical Director, Region C
Richard W. Whitten, MD, MBA, FACP, Medical Director, Region D

University of Pittsburgh

Human Engineering Research Laboratories

6425 Penn Avenue, Suite 400
Pittsburgh, PA 15206
412-822-3700
Fax: 412-822-3699
www.herl.pitt.edu

School of Health and Rehabilitation Sciences
Department of Rehabilitation Science and Technology

School of Medicine
Department of Physical Medicine and Rehabilitation

Executive Faculty:

Rory A. Cooper, Ph.D.
Director
Distinguished Professor and FISA/PVA Chair
Rehabilitation Science and Technology
Professor
Physical Medicine and Rehabilitation and Bioengineering

Michael L. Boninger, M.D.
Medical Director
Chair
Physical Medicine and Rehabilitation
Professor
Rehabilitation Science and Technology and Bioengineering

Brad E. Dicianno, M.D.
Associate Medical Director
Associate Professor
Physical Medicine and Rehabilitation

Jon Pearlman, Ph.D.
Associate Director of Engineering
Assistant Professor
Rehabilitation Science and Technology

Alicia Koontz, Ph.D., ATP, RET
Associate Director for Research Capacity Building
Associate Professor
Rehabilitation Science and Technology

January 14, 2013

Susan Miller, MD
U.S. Department of Health & Human Services
Centers for Medicare Services
OA/OCSQ/CAG/DID
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. Miller,

We are writing this letter because we are aware that CMS staff and its contractors are currently assessing coding and coverage policies regarding certain manual wheelchairs. The technologies currently classified as K0009 are categorized as such because they have unique features and functions important to people with disabilities which are dissimilar from technologies in other existing codes. Some examples of products that fall within the K0009 codes are:

- Custom made to measure manual wheelchairs (Quickie GTi Titanium; TiLite TR, TX, ZR; Colours Zephyr; Invacare Crossfire Titanium; Terminator Everyday)
- Positional tilt <45 degrees wheelchairs (PDG Bentley, Fuze T20, LaBac BTC)
- Bariatric wheelchairs with special features (PDG Eclipse 600, Sunrise M6)
- Standing manual wheelchairs (Lifestand, Permobil Helium)

We are requesting that special consideration be made for coding of these categories of chairs. We wish to point out the distinct nature of these products and request that the coding be applied such that coverage of these products is consistent with the design, intent, and clinical use of the technologies as compared to technologies in already established HCPCS codes.

As the Medical Director and Associate Medical Director of the Human Engineering Research Laboratories, and the Medical Director of the UPMC Center for Assistive Technology, we wish to discuss the body of scientific literature that supports the need to code these chairs in a way that acknowledges the medical purposes of their features.

University of Pittsburgh

Human Engineering Research Laboratories

6425 Penn Avenue, Suite 400
Pittsburgh, PA 15206
412-822-3700
Fax: 412-822-3699
www.herl.pitt.edu

The Human Engineering Research Laboratories is a joint venture between the VA Pittsburgh Healthcare System and the University of Pittsburgh. Our research is funded by federal organizations such as the VA, NIH, the Centers for Disease Control, NIDRR, and others. Our research aims to continuously improve the mobility and function of people with disabilities through advanced engineering in clinical research and medical rehabilitation. We are a VA Center of Excellence in Wheelchairs and Associated Rehabilitation Engineering. We also lead NIDRR Model Centers on Spinal Cord Injury and Traumatic Brain Injury Research and Care.

There is a considerable published research that supports the unique features of the products listed above as being medically necessary. Wheelchair setup and configuration has a significant impact on function. Proper setup and configuration of a manual wheelchair is essential for minimizing the forces at the shoulder. High forces at the shoulder can result in shoulder pain and injury, as well as cause significant disability. Over time, a wheelchair user with upper limb injury may then require higher levels of care and more expensive mobility equipment, not to mention have lower levels of functional independence and reduced quality of life. Research has also shown that having the ability to adjust axle position, seat inclination, back angle and other features can reduce forces and thus prevent injury to the shoulder. Proper position of the axle can improve the efficiency and safety of wheelchair propulsion. Moreover, the weight of the wheelchair itself is directly related to risk of shoulder injury.

There are limitations to published research in this area. Complex rehabilitation technology (CRT) is customized to the individual, resulting in a myriad of configurations and technologies that prevent us from conducting randomized, controlled trials. Broad and inadequately defined codes (groupings of dissimilar equipment) create barriers to comparative effectiveness research that might inform better coverage policies for CRT. Population sizes may be limited by small scales of the populations that use CRT in general, and even smaller sample sizes for specific technology or configurations. Additionally, there may be tension between internal and external validity. Attempting to isolate what is causing an outcome may improve internal validity but also may diminish external validity by not reflecting the reality of the population of users of the technology. As a result, efficacy studies may not answer all questions about who the device is appropriate for or when it is needed. It may be challenging to account for varying environmental and personal factors (in addition to all the custom configurations previously discussed) in such research.

We recognize that a goal of CMS is to seek out reliable evidence to inform policy decisions. However, evidence based practice and policy development integrate the best available research evidence with clinical expertise and patient values. In fact, the CMS National Coverage Decision for Mobility Assistive Equipment recognizes that a manual wheelchair should be "optimally configured" (in terms of seating options, wheelbase, device weight, and other appropriate accessories) for this determination. As such, it is our professional opinions and years of clinical practice and research that lead us to conclude that the findings in our current body of literature and clinical guidelines support this policy. In fact, our own research has been the basis of clinical practice guidelines on the preservation of upper limb function in spinal cord injury, which are followed worldwide in the care of individuals with not only spinal cord injuries but also many other similar conditions. These guidelines include the proper setup and configuration of manual wheelchairs as a crucial component of medical and rehabilitative care.

University of Pittsburgh

Human Engineering Research Laboratories

6425 Penn Avenue, Suite 400
Pittsburgh, PA 15206
412-822-3700
Fax: 412-822-3699
www.herl.pitt.edu

It is also important to highlight the fact that while much of the current research has been conducted in populations of patients with spinal cord injury, the functional considerations for other populations are comparable. Upper limb weakness, trunk instability, musculoskeletal injuries, and other factors that affect positioning and propulsion of a wheelchair are seen in patients with stroke, multiple sclerosis, muscular dystrophies, cerebral palsy and many others. Thus, extrapolation of research findings in studies involving spinal cord injuries is clinically relevant and appropriate for other populations. That is, the recommendations for configuration of a chair to reduce the risk of upper limb injury is similar for these groups.

In summary, it is our professional opinions that CMS should make special consideration for the coding of these products to recognize the design, intent, and clinical use of the technologies. The body of scientific literature supports the medical indications for use of these technologies for individuals with a variety of disabilities. Because of their special features, the products listed above as coding into K009 cost more to produce. Without appropriate coding, the products will disappear from the market and our patients and CMS beneficiaries will suffer.

Should you have any questions concerning our recommendations or research, please do not hesitate to contact us directly.

Sincerely,

Michael Boninger, MD
Professor, Rehabilitation Science and Technology and Bioengineering
Medical Director, Human Engineering Research Laboratories
Chair, Physical Medicine and Rehabilitation

Brad E. Dicianno, MD
Associate Professor
Medical Director, Center for Assistive Technology
Associate Medical Director, Human Engineering Research Laboratories

CC: Stacey V. Brennan, MD, Medical Director, Region B
Paul J. Hughes, MD, Medical Director, Region A
Robert D. Hoover, Jr., MD, MPH, FACP, Medical Director, Region C
Richard W. Whitten, MD, MBA, FACP, Medical Director, Region D

RANCHO LOS AMIGOS
NATIONAL REHABILITATION CENTER

Los Angeles County
Board of Supervisors

Gloria Molina
First District

Mark Ridley-Thomas
Second District

Zev Yaroslavsky
Third District

Don Knabe
Fourth District

Michael D. Antonovich
Fifth District

Jorge Orozco
Chief Executive Officer

Robin Bayus
Acting Chief Operations Officer

Mindy Aisen, MD
Chief Medical Officer

Karen Wunch, RN
Chief Nursing Officer

7601 E. Imperial Highway
Downey, CA 90242

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January 18, 2013

Susan Miller; MD
U.S. Department of Health & Human Services
Centers for Medicare Services
OA/OCSQ/CAG/DID
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. Miller;

I am aware that CMS staff and its contractors are currently assessing coding and coverage policies regarding certain manual wheelchairs. I am writing to share my perspective resulting from my experience in the research and clinical study of shoulder function for individuals with spinal cord injury who use wheelchairs (WC).

I am the Director of the Pathokinesiology Laboratory at Rancho Los Amigos National Rehabilitation Center. For the past two decades our federally funded research at the Pathokinesiology Laboratory has focused on shoulder function in individuals with spinal cord injury (SCI) who use WCs. The incidence of shoulder joint pain in the SCI population was found to be significantly greater than that seen in the normal population for every age group. To prevent further loss of functional independence for those with SCI, it was imperative to find ways to reduce the strain and joint deterioration that may occur with prolonged WC use. Our early research sought to understand the causes and identify solutions for the high rate of shoulder pain experienced after SCI. We identified that superiorly directed reaction forces were created at the shoulder as a direct consequence of upper extremity weight bearing during WC propulsion and moderate to high intensity muscle activity was elicited to control these shoulder forces {Mulroy 1996; Kulig 2001}. If the demands of controlling the weight bearing forces exceed the strength of these muscle groups, the muscles fatigue and mechanical impingement occurs. Prolonged impingement leads to degenerative changes in the tendons of the rotator cuff and eventually to partial or complete tears, chronic pain, and reduced function as well as decreased quality of life {Gutierrez, 2007}.

Once we gained a clearer picture of the functional demands of upper extremity weight-bearing during WC propulsion, we began to investigate potential solutions including adjusting the wheelchair seat position to reduce damaging forces on the shoulder, and designing methods of manual wheelchair propulsion that are less stressful to the shoulder structures. We identified that moving the WC seat so that the shoulder was posterior to wheel axle significantly reduced the peak superior shoulder joint force and shoulder muscle intensity in all WC propulsion conditions {Mulroy, 2005; Gutierrez 2005}. Similarly, a lever-driven WC propulsion system redirected the vertical shoulder joint reaction force to a more horizontally directed force and reduced the intensity of muscle activity in the important rotator cuff muscles {Requejo 2008}. These findings are important because the vertical forces at the shoulder are those that are most likely to cause the shoulder joint to slide upwards and impinge the tendons of the rotator cuff.

Our most recent research documented the risk factors for developing shoulder pain after SCI. We found evidence that the magnitude of the medial force at the shoulder and a more forward location of initial hand contact with the push rim are significant risk factors for the development of shoulder pain in individuals with long standing SCI {Mulroy, 2013}. Development of shoulder pain was also associated with a more anterior position of the shoulder relative to the rear wheel. These findings are consistent with our previous studies that demonstrated that a more posterior seat position (and consequently shoulder position) resulted in a more posterior hand contact and significant reduction in the shoulder joint forces and intensity of muscle activity.{Mulroy 2005, Gutierrez 2005}

We also identified that increased shoulder muscle strength (particularly in the adductors, external rotators, and abductors) was a protective factor that reduced the risk of shoulder pain development. Moreover, increased shoulder muscle strength reduced the impact of the negative WC propulsion risk factors. Those who eventually developed shoulder pain were less active even prior to the onset of shoulder pain than those who remained pain free. They performed fewer transfers and car transfers and propelled at a slower velocity on a daily basis ("marginal self propeller") than those who remained pain free. The combination of reduced activity and decreased shoulder muscle strength prior to shoulder pain development in those who would eventually develop shoulder pain underscores that their reduced shoulder muscle capacity was inadequate for the daily demands of upper extremity weight bearing after SCI limiting their functional activity in the community and creating an increased risk for shoulder pain development.

Our research taken as a whole provides strong evidence that multiple solutions are necessary to address this clinical problem including increasing the individual's capacity by muscle strengthening programs as well as reducing the demands on the shoulder by optimizing the fit of the WC for each person. Our research identified seat position in relation to the rear wheel, as determined by the axle position, as a primary WC adjustment to optimize the fit of the WC to an individual. While seat position was the primary WC adjustment that we studied directly in our research, many other WC adjustments can also impact position of the shoulder in relation to the push rim (and location of hand contact on the push rim) including seat pan tilt, chair width, and camber of rear wheels. In order to ensure long-term upper extremity function in persons who rely on manual WC propulsion for mobility, it is imperative to have the adjustability in their WC to optimize their individual biomechanics of propulsion.

Our NIDRR funded review article *Evidenced-Based Strategies to Preserve Shoulder Function in Manual Wheelchair Users with Spinal Cord Injuries* {Requejo, Mulroy et al. 2008} addresses strategies to reduce shoulder joint loading and muscular demands to increase the shoulder's capacity to handle loads during manual wheelchair activities in full time WC users. This article presents important research issues for evaluating and decreasing the shoulder demands during WC activities by adopting the recommendations put forth in the Paralyzed Veterans of America's Consortium for Spinal Cord Medicine's guideline titled "Preservation of Upper Limb Function Following Spinal Cord Injury: A Clinical Practice Guideline for Health-Care Professionals"} that were based on the most current scientific and professional information available for preserving shoulder function in manual wheelchair users with SCI. These recommendations include optimizing environmental factors related to reducing the mechanical load and muscular demands through ergonomics, equipment selection, training, and environmental adaptations and personal factors related to increasing the capacity of shoulder joint structures to handle the mechanical loads through strengthening and exercise. Each recommendation is supported by current research in each relevant area. **While our research has focused on individuals with SCI, the problem of shoulder joint pain and the practice guideline recommendations are relevant to all individuals who must use manual WC propulsion as a primary means of mobility.** Indeed, many of the original demographic studies documenting the prevalence of shoulder pain with WC use surveyed a heterogeneous population of people with many different diagnoses resulting in manual WC use.

The CMS National Coverage Decision for Mobility Assistive Equipment recognizes that a manual WC should be "optimally configured" [emphasis provided] (seating options, wheelbase, device weight, and other appropriate accessories) for this determination. The evidence and clinical guidelines support this policy. It is important to understand that there is a body of research to support this policy statement, specifically in the areas of wheel placement, seat position, WC components etc. It is my professional opinion based on years of clinical practice and research that lead me to conclude that these findings can be generalized to populations with diagnoses other than SCI but with comparable functional presentations.

Should you have any questions concerning my recommendations or research, please do not hesitate to contact me directly.

Sincerely,

Sara Mulroy, PT, PhD
Director, Pathokinesiology Laboratory
Rancho Los Amigos National Rehabilitation Center
Downey, CA

RANCHO LOS AMIGOS
NATIONAL REHABILITATION CENTER

CC: Stacey V. Brennan, MD, Medical Director, Region B
Paul J. Hughes, MD, Medical Director, Region A
Robert D. Hoover, Jr., MD, MPH, FACP, Medical Director, Region C
Richard W. Whitten, MD, MBA, FACP, Medical Director, Region D

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Dalhousie University

Dr. R. Lee Kirby
Division of Physical Medicine & Rehabilitation
Department of Medicine
Nova Scotia Rehabilitation Centre site
1341 Summer Street
Halifax, NS B3H 4K4
Phone: (902) 473-1268
Fax: (902) 473-3204
E-mail: kirby@dal.ca

January 14, 2013

Susan Miller, MD
U.S. Department of Health & Human Services
Centers for Medicare Services
OA/OCSQ/CAG/DID
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. Miller;

I am aware that CMS staff and its contractors are currently assessing coding and coverage policies regarding certain manual wheelchairs. I am writing to share my perspective resulting from my clinical experience providing physical medicine and rehabilitation services to people with chronic long term disabilities and my research related to safety and performance of wheelchairs.

I am a Professor in the Division of Physical Medicine and Rehabilitation in the Department of Medicine at Dalhousie University in Halifax, Nova Scotia, Canada. At our laboratory at the Nova Scotia Rehabilitation Centre Site of the Queen Elizabeth II Health Sciences Centre, we conduct research related to the safety and performance of wheelchairs. I lead the Wheelchair Research Team that developed the Wheelchair Skills Program, a low-tech, high-impact training program (www.wheelchairskillsprogram.ca).

In my 37-year career, I have published over 130 papers in peer-reviewed journals and over 275 minor publications (abstracts, proceedings, etc). Most of these publications relate to wheelchair issues. I am a member of the RESNA Board of Directors and a member of two editorial boards. I spent over 10 years as a member of the RESNA/ANSI Wheelchair Standards Committee as well as the ISO Wheelchair Standards Committee.

Although there remain many research questions to answer about wheelchairs, the accumulated body of knowledge about wheelchairs is quite impressive. Most wheelchair experts, of whom I count myself one, understand that the characteristics of the wheelchair and how it is set up for the individual wheelchair user can have a profound effect on safety and performance. Safety issues relate both to acute accidents and to overuse injuries of the upper limbs. The WHO guidelines on the provision of wheelchairs is very clear about the importance of selecting the optimum wheelchair for the user, adjusting it to fit him/her and training him/her in its use. Available adjustments include rear axle position, seat height, seat width, seat-back angle, tilt and recline.

In summary, one cannot overemphasize the importance of an optimally configured manual wheelchair for individuals who depend upon such a wheelchair for their daily activities in varying environments.

Should you have any questions concerning my comments or research, please do not hesitate to contact me directly.

Sincerely,

Lee Kirby, MD, FRCPC
Professor

Cc: Stacey V. Brennan, MD
Paul J. Hughes, MD
Robert D. Hoover, Jr., MD, MPH, FACP
Richard W. Whitten, MD, MBA, FACP

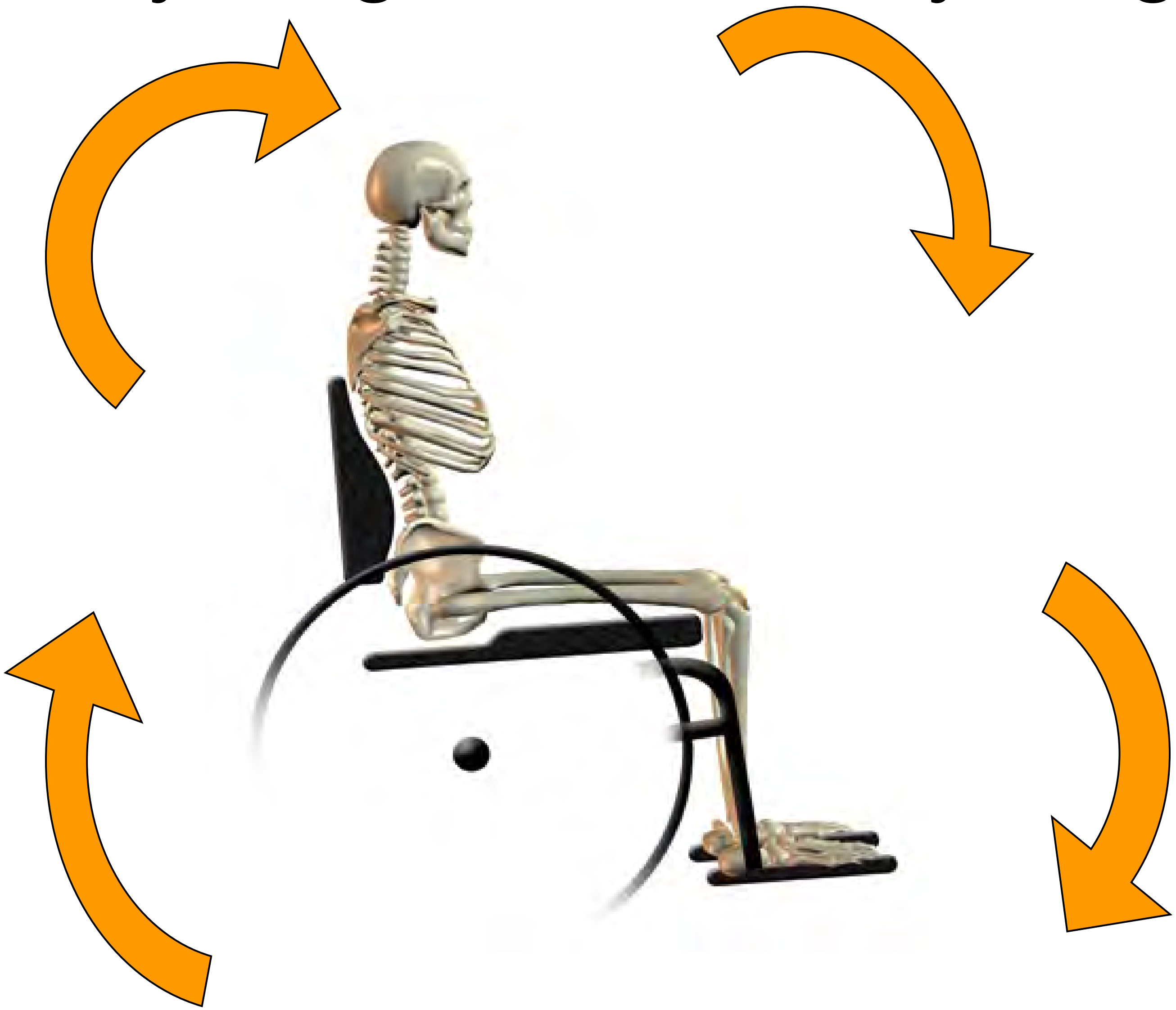
K0009 Product Characteristics: Definitions and Benefits

January 28, 2013

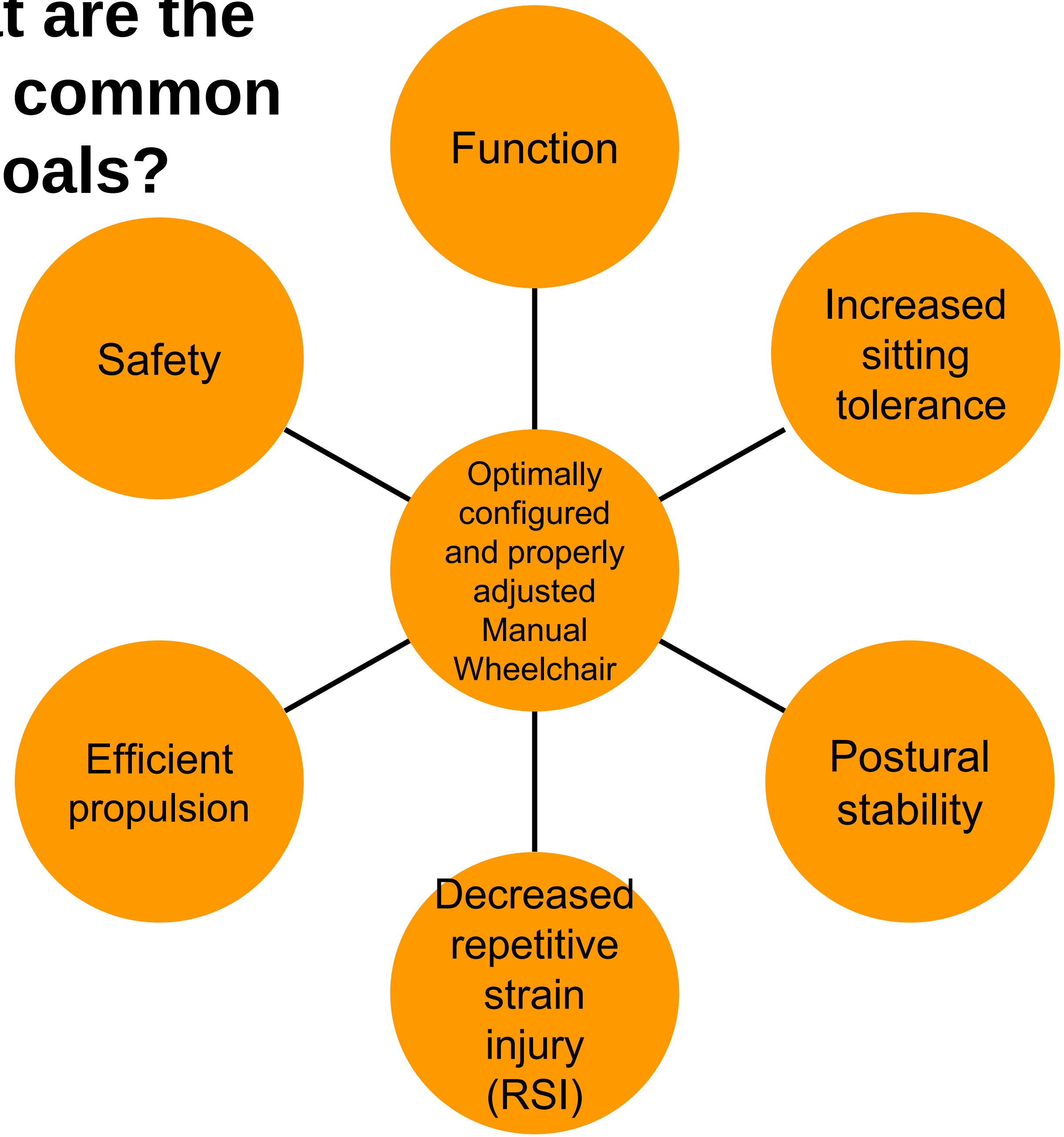
Definitions and Benefits

The following slides contain definitions and benefits for terms used within the product characteristics spreadsheets. The terms, definitions and benefits are the results of months of effort by manufacturers and clinicians to provide a basis for understanding the configurability and adjustability of complex rehab technology (CRT) and their clinical importance

Configuration and Adjustability Everything effects everything!



What are the most common Goals?



Capability

Definition	Benefit
The chair can be supplied by the manufacturer according to specified dimensions and required characteristics	The ability to order the chair in a specific configuration or with specific options provides the client with the system that is optimally tailored to meet their functional and medical needs most effectively.

Adjustability

Definition	Benefit
Adjustments can be made with the components supplied at initial purchase of the chair. May require the use of tools. .	Adjustable components provide a means to configure the chair to meet the user's current functional and medical needs. These components also provide a means to alter this configuration to accommodate changing needs throughout the day or to accommodate changes that result from growth, progressive or changing conditions and/or aging. .

Frame Depth

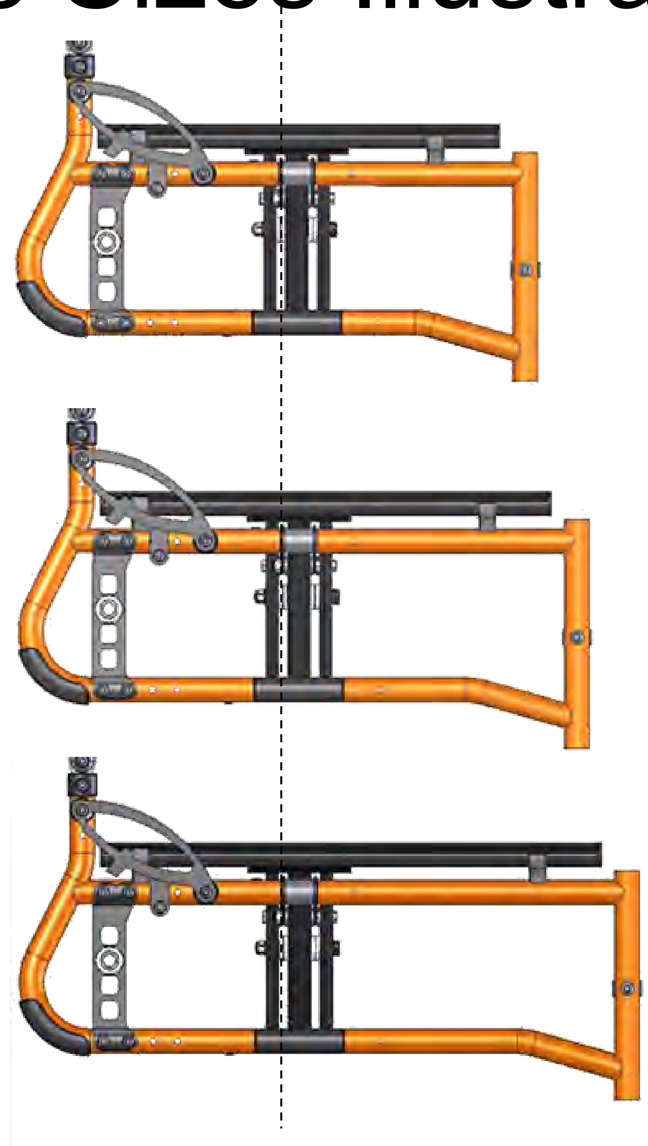
Definition

The horizontal measurement of the length of the frame between the attaching point of the caster stem and the attaching point of the rear wheels. If the chair offers adjustable rear wheel position and/or adjustable caster mounting, measurement must be from the most rearward position. Changes in this dimension results in variation of the distance between the back canes and the footrests.

Benefit

The option to choose the appropriate frame depth provides the ability to fit the chair to the user's needs and medical condition. Proper seat depth provides support for the lower extremities to help maintain optimal pelvic and lower extremity position, prevent postural deformities and provide maximal pressure distribution to prevent skin breakdown. Providing an appropriate frame depth for each seat depth maintains the appropriate relationship between the frame and the user in regards to knee angle and weight distribution. It also maintains optimal stability of the chair and appropriate weight over the casters.

Frame Depth
Three Sizes Illustrated



Seat Depth Adjustability

Definition

Provides a means of adjustment of seat depth through forward extension of seat rail or equivalent. (May require a qualified technician to change).

Benefit

This adjustment allows the chair to be properly fit and subsequently changed as the user's needs for seat depth change. Seat depth requirements can change due to growth or due to changes in body mass or positional needs. A change in seat depth is also required to accommodate a change in the type or the thickness of the back support. This adjustment provides the appropriate seat depth but does not maintain the same relationship between the frame and the user in regards to knee angle or stability and weight distribution. Proper seat depth in combination with appropriate seating provides support for the lower extremities to help maintain pelvic and lower extremity positioning, prevent postural deformities and provide appropriate pressure distribution.

Seat Frame Depth Adjustability

Definition

Provides a means of adjustment of seat depth through adjustment of the structural components of the frame without additional components unless supplied with the chair at initial issue. Changes in this dimension result in variation of the distance between the back canes and the footrests. May require the use of tools. (May require a qualified technician to change).

Benefit

This adjustment allows the chair to be properly fit and subsequently changed as the user's needs for seat depth change. Seat depth requirements can change due to growth or due to changes in body mass or positional needs. A change in seat depth may also be required to accommodate a change in the type or the thickness of the back support. This adjustment provides the appropriate seat depth while also maintaining the same relationship between the frame and the user in regards to knee angle, as well as stability and weight distribution. Proper seat depth in combination with appropriate seating provides support for the lower extremities to help maintain pelvic and lower extremity positioning, prevent postural deformities and provide appropriate pressure distribution.

Seat Width

Definition	Benefit
The horizontal measurement across the seat frame from one seat rail to the other.	The proper fit of the wheelchair is critical to maximizing function and medical condition. Proper seat width provides support for the pelvis to help maintain optimal pelvic, trunk and lower extremity position, prevent postural deformities and provide maximum pressure distribution to prevent skin breakdown. Proper seat width can also allow optimal access to upper extremity support surfaces/armrests and access to rear wheels for propulsion.

Benefits of More Seating Widths

- Inappropriate seat width can:
  - Cause postural deformities
  - Decrease function
    - Decrease UE wheel access
  - Create discomfort
  - Decrease sitting tolerance
  - Affect accessibility
- Standard sizes fit “some” not “all”

Good size Too wide

Seat Frame Width Adjustability

Definition

Allows for adjustment of seat/frame width by adjustment of the structural components of the frame and/or is offered with at least one growth adjustment kit at no charge for components. May require the use of tools. (May require a qualified technician to change.)

Benefit

This adjustment allows the chair to be properly fit and subsequently changed as the user's needs for seat width size change. Proper seat width provides support for the pelvis to help maintain optimal pelvic, trunk and lower extremity position, prevent postural deformities and provide maximum pressure distribution to prevent skin breakdown. Proper seat width can also allow optimal access to upper extremity support surfaces/armrests and access to rear wheels for propulsion. Seat width requirements can change due to growth, changes in body mass or positional needs, or the need to accommodate orthotics or prosthetics. A change in seat width might also be required to accommodate changes in wheelchair accessories required for function or medical need.

Seat Frame Angle Capability (Seat Inclination)

Definition

The angle of the seat relative to the horizontal plane. The value indicates the minimum angular capability available.

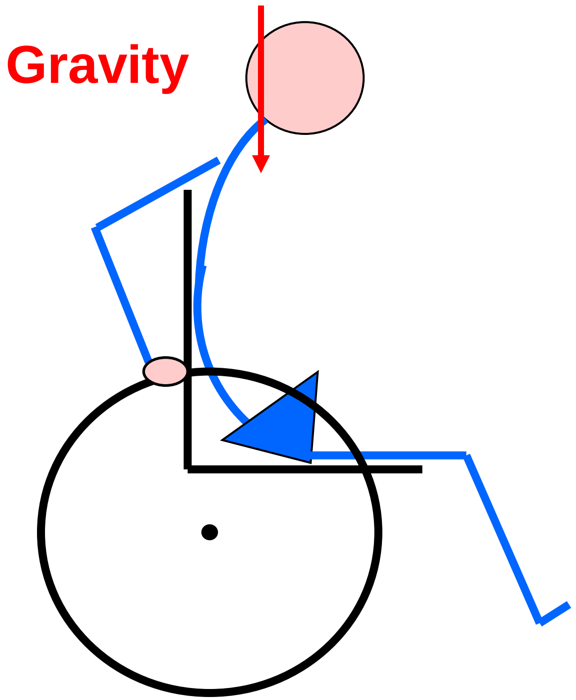
Benefit

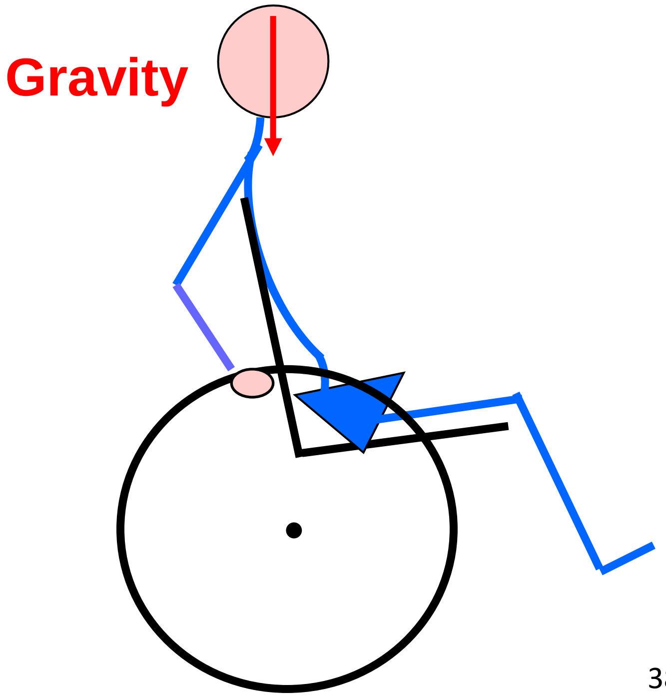
The appropriate seat frame angle provides the client with the orientation of the seating system/surfaces within the chair that will help maximize function and meet medical needs. The seat angle can affect the client's ability to maintain an upright posture against gravity and the client's level of fatigue. The correct seat angle can provide stability and balance and facilitate optimal use of the trunk and back support/shape. This can improve stability required for upper extremity function, improve head control, and help prevent postural deformities and the resulting physiological and functional complications. These complications can include respiratory and gastrointestinal issues, skin breakdown, and interference with the ability to efficiently propel the wheelchair (with upper and/or lower extremities) and/or participate in ADL's and/or IADLs. The appropriate seat angle can also provide optimal visual field/forward line of sight.

Seat Frame Angle (Seat Inclination)

Seat Frame Angle (Seat Inclination)

Minimal fixed tilt /seat “dump” can have significant effect on posture, visual orientation and wheel access





Seat Frame Angle Adjustability

Definition

Provide a means to adjust the seat angle relative to the horizontal plane without additional components unless supplied with the chair at initial issue. May require the use of tools and must not effect the perpendicular alignment of the caster housing. (May require a qualified technician to change.)

Benefits

Seat angle adjustment provides the ability to change the orientation of the chair to match the client's function and medical needs. For clients with decreased ability to maintain an upright posture against gravity, a specific angle (or tilt) will minimize the negative effects of gravity, decrease the fatigue that results from maintaining an upright posture, provide stability and balance, and facilitate optimal use of the trunk and back support/shape. This may also be required for upper extremity function, improved head control, and prevent to postural deformities and the resulting physiological and functional complications. These complications can include respiratory and gastrointestinal issues, skin breakdown, and interference with the ability to efficiently propel the wheelchair and/or participate in mobility-related activities of daily living (MRADLs). A specific angle (or tilt) can also provide improved visual field/forward line of sight. For clients with good posture and balance, a more upright orientation of the seat is used to assist in participation in MRADLs and to provide optimal access to the environment. This is also used by clients who are propelling the chair with one or both lower extremities.

Rigid Front Frame Angle

- Tighter front frame/hanger angles
  - Shorter overall length for accessibility and maneuverability
  - Tighter knee angles
  - Accommodate limitation in knee flexion
  - Load the foot

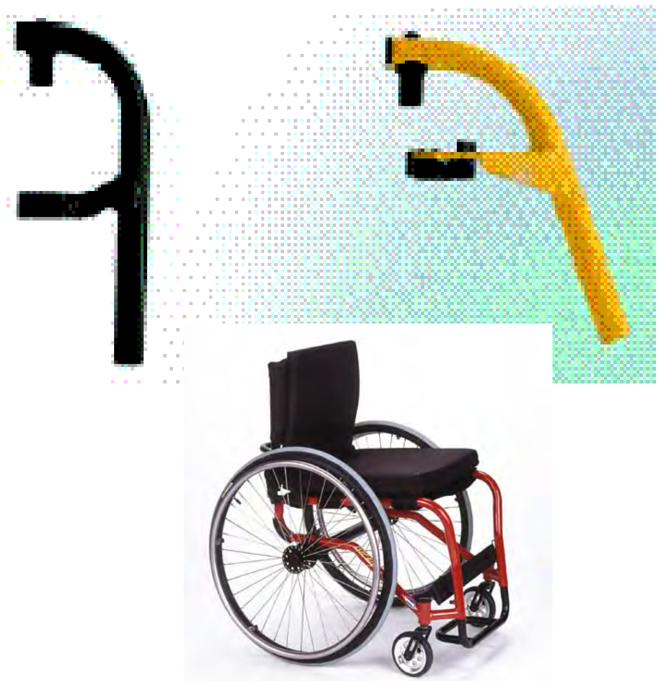
Front Rigging- Frame Angle

- Optimize sitting footprint – load the feet
- Optimize turning radius – feet as close to body as possible
- Respect hamstrings and unique foot angles/positions

Angle for Removable Footrest or Front Frame Member

Definition

Provides a specific angle of the footrest hanger relative to the seat surface



Benefits

A specific footrest angle is needed to place the lower extremity in the position that will maintain good pelvic position and provide optimal pressure distribution. The appropriate hanger angle may be used to accommodate any decreases in knee range of motion (flexion or extension), accommodate tight hamstrings, accommodate long leg lengths on low seat to floor heights, decrease pain, or even increase sitting tolerance. Positioning the client's knee at a specific angle can be used clinically to decrease spasticity. The hanger angle can also affect overall length and maneuverability of the chair.

Seat to Floor Height

Definition

The vertical measurement from the floor to the seat surface

Benefits

Proper seat to floor height is important to facilitate safe and effective transfers and provide optimal access to the environment in order to allow participation in mobility-related activities of daily living (MRADLs). The correct seat to floor height also allows the client to reach the ground for effective foot propulsion and/or provide sufficient ground clearance for footrests.

STFH-Vertical Wheel Position

STFH too low:

- Increased pressure on ischials
- Posture compromised
- Inadequate ground clearance
- Environmental access compromised
- Transfers ?

STFH too high:

- Cannot reach ground to foot propel
- Environmental access compromised
- Transfers affected?
- Posture compromised

STFH-Vertical Adjustment

Considerations

- Rear wheel access
- Foot propulsion
- Transfers
- Reaching
  - Overhead
  - To the floor
- **Clearance**
  - Under tables / desks
  - For foot plate

Back Height

Definition

The vertical measurement of the back surface from the seat rail or horizontal seat frame to the top of the back upholstery

Benefits

Proper back height is critical to provide support for optimal posture, stability, balance, and to provide maximum sitting tolerance, while not interfering with upper extremity function. The appropriate back height also allows optimal rear wheel access for propulsion and optimal participation in mobility-related activities of daily living (MRADLs) while in the chair.

Back Height Adjustment

Definition

Provides a means of changing the back height by adjustment of the structural components of the frame without additional components unless supplied with the chair at initial issue. May require the use of tools. (May require a qualified technician to change.)

Benefits

This adjustment allows the chair to be properly fit to the user or subsequently changed as the user grows or as their functional needs change. Proper back height is critical to provide support for optimal posture, stability and balance and to provide maximum sitting tolerance, while not interfering with upper extremity function.. The appropriate back height also allows optimal rear wheel access for propulsion and optimal participation in mobility-related activities of daily living (MRADLs) while in the chair. For many clients, the specific back height required can change over the lifespan of the chair. Adjustment of this parameter can eliminate the need to prematurely replace the wheelchair.

Seat to Back Angle

- Closed seat to back angle (“squeeze”)
  - Secure the pelvis and reduce risk of sliding
  - Encourage upright trunk
  - Reduce extensor spasticity

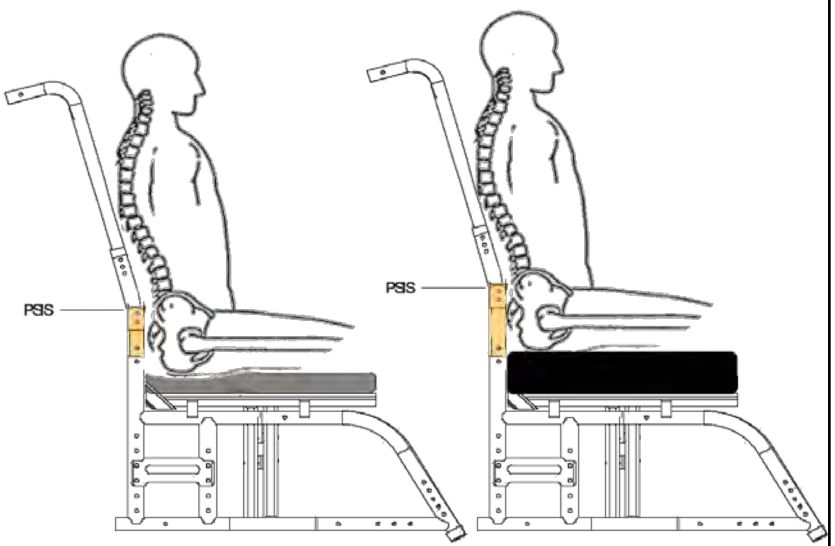
Back adjustments

- Back adjustability
  - Height
  - Angle

Seat to Back Angle

Definition

The angle of the back canes relative to the seat



Benefits

A seat to back angle greater than or less than 90 degrees can be used to: accommodate fixed thoracic kyphosis, posterior pelvic tilt or hip contractures; provide for improved visual field/forward line of sight; improve respiratory function; provide postural stability and balance; improve head / neck positioning for swallowing; and manage abnormal tone. The seat to back angle adjustment can also be used to create a squeeze seat to help maintain an upright back, when used in conjunction with lowering the rear seat to floor height.

Seat To Back Angle Adjustability

Definition

Provides a means to adjust the angle of the back relative to the seat without affecting the seat angle relative to the horizontal and without additional components unless supplied with the chair at initial issue . May require the use of tools. (May require a qualified technician to change.)

Benefits

This adjustment allows the chair to be properly fit to match the user's current postural and/or orthopedic needs, while also allowing for adjustment to accommodate later changes in orthopedic or neuromuscular condition. A seat to back angle greater than or less than 90 degrees may be required to accommodate: fixed thoracic kyphosis, posterior pelvic tilt or hip contracture; provide for improved visual field/forward line of sight; improve respiratory function; provide postural stability and balance; improve head / neck positioning for swallowing; and manage abnormal tone. The seat to back angle adjustment can also be used to create a squeeze seat to help maintain an upright back, when used in conjunction with lowering the rear seat to floor height. For users who have medical conditions that change over the lifespan of the chair, this adjustment can eliminate the need to prematurely replace the wheelchair.

Rear Wheel Axle Adjustments

Adjustable Rear Wheel Position

- Adjust horizontal, vertical, lateral position and camber using adjustable axle plate or camber tube

Horizontal position affects:

- Wheel access/UE position
- Maneuverability
- COG/stability

Lateral position affects:

- Wheel access/UE position
- Overall width

Vertical position affects:

- Wheel access/UE position
- STFH
- Orientation in space

Camber affects:

- Wheel access/UE position
- Maneuverability
- Stability

Fully Adjustable Axle Position

- Multiple horizontal, vertical and lateral adjustments that change rear wheel position
- Moving the rear wheel affects:
  - Access to the handrim
  - UE position during each stroke
  - STFH
  - Orientation of the frame
  - Efficiency of the wheelchair

Rear Wheel Position Adjustability - Horizontal

Definition

Provides a means of adjustment of the horizontal position of the rear wheels from the plane of the rear frame at the intersection of the vertical plane of the axle, forward in a maximum of 1/2" increments. Can be adjusted in the field without additional components unless supplied with the chair at initial issue. May require the use of tools. (May require a qualified technician to change.)

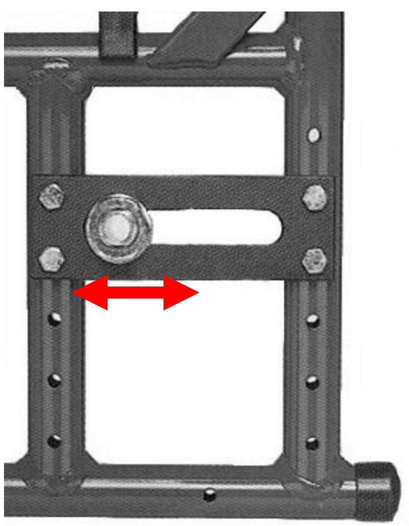
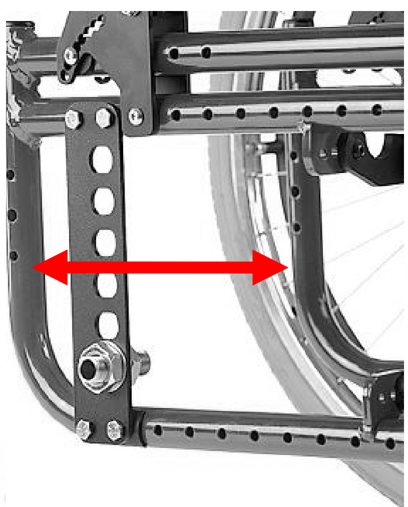
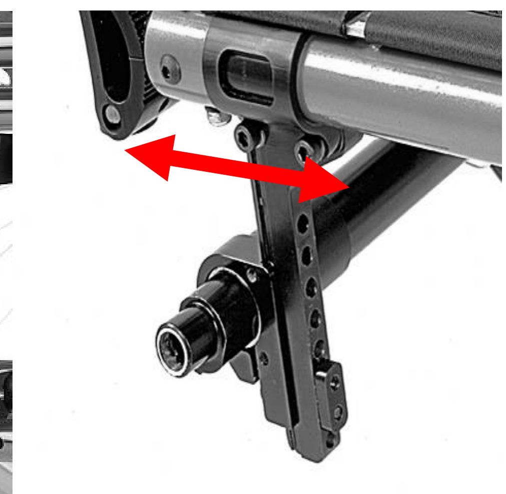
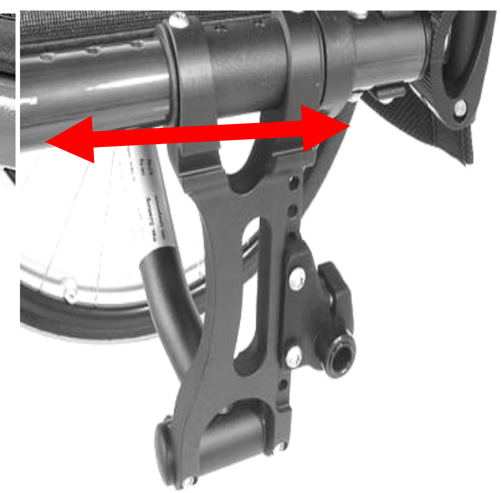
Benefits

Horizontal adjustment of the rear wheel in relationship to the frame affects the user's access to the rear wheel for propulsion, the weight distribution of the client and seating system over the base, turning radius, as well as the overall length of the chair. Maximizing wheel access can increase the efficiency of propulsion, reduce the risk of repetitive strain injuries of the upper extremities, and reduce fatigue and increase endurance while propelling. Adjusting the weight distribution can affect the rearward stability as well as the responsiveness of the chair during propulsion. Adjusting the overall length of the chair and the turning radius affect maneuverability and environmental access. The ability to adjust this parameter provides the user with the best combination of stability and wheel access and this can be re-adjusted as the user's needs change due to a change in function or size.

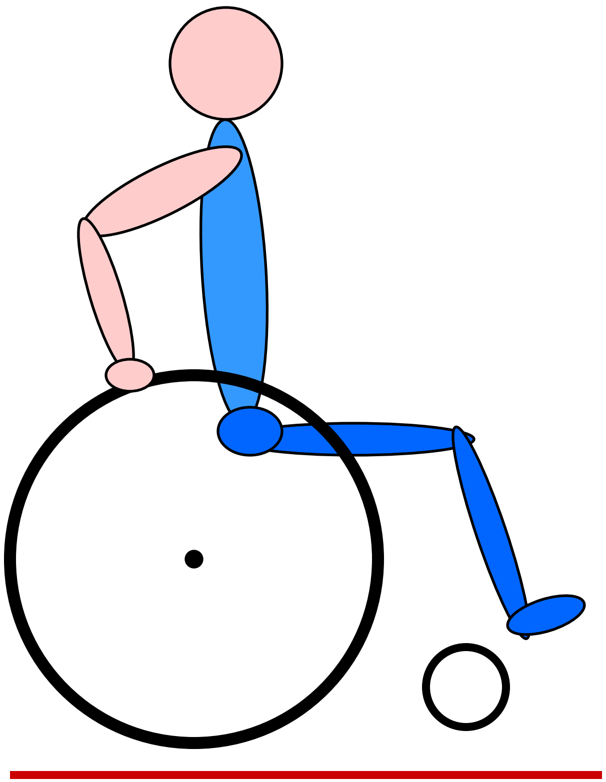
Horizontal Rear Wheel Position

To change horizontal wheel position:

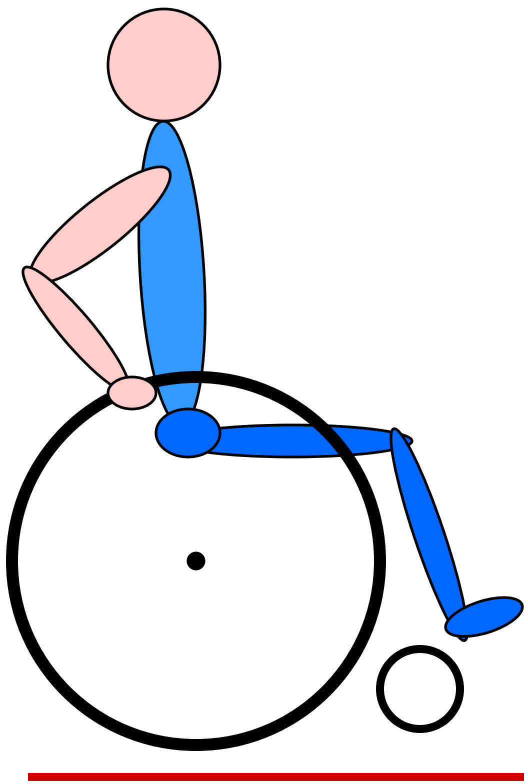
- Move axle sleeve horizontally in axle plate
- Move axle plate horizontally on frame
- Move camber tube horizontally on frame

Horizontal Rear Wheel Position

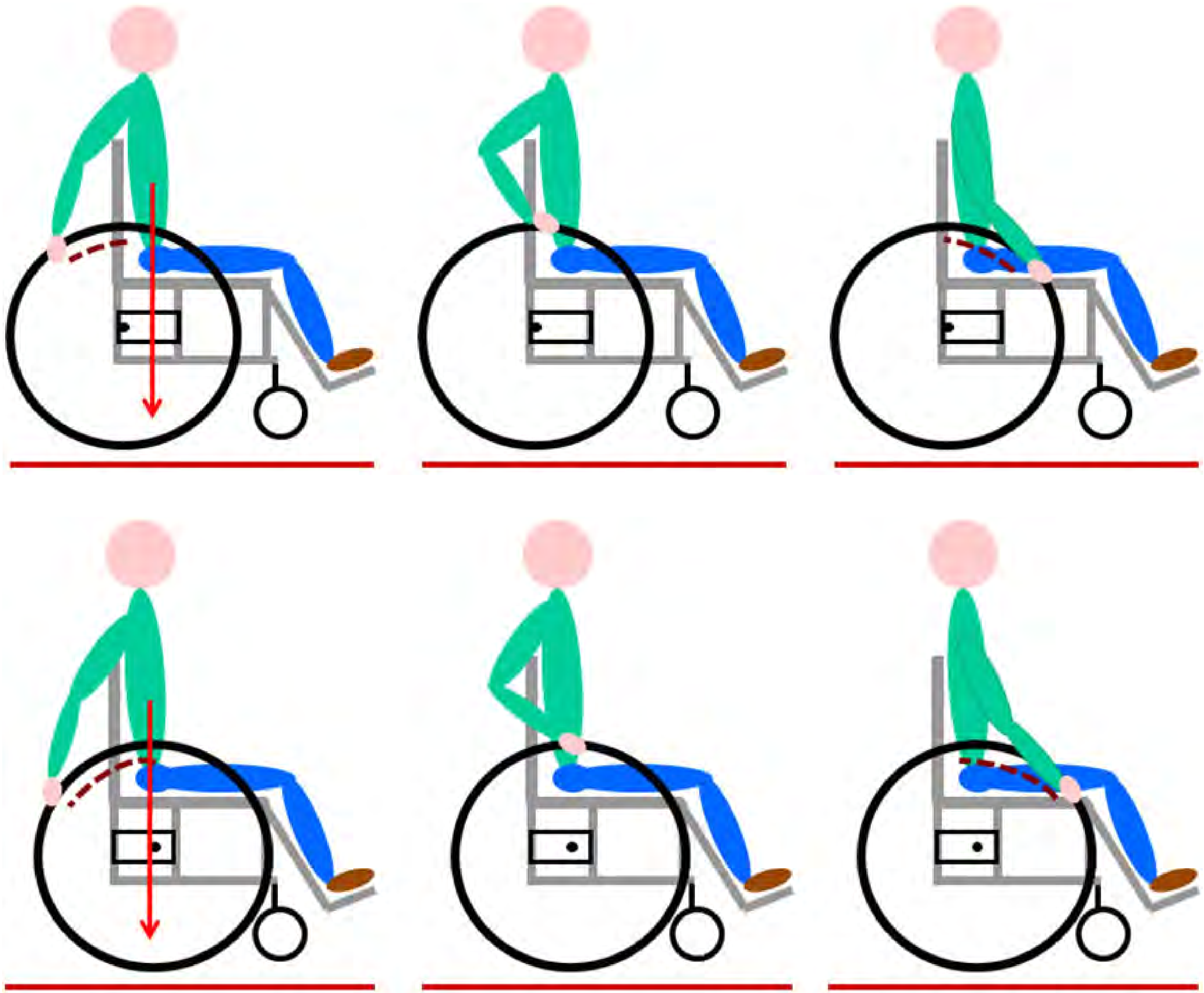


Wheels Rearward= Seat Anterior



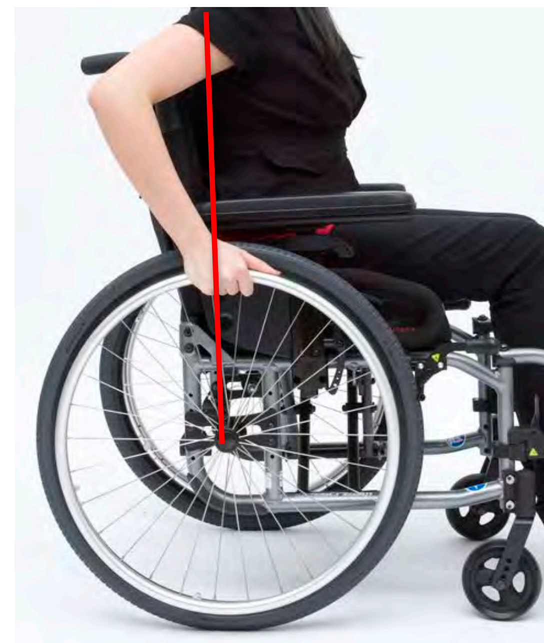
Wheels Forward= Seat Posterior

Horizontal Adjustments



Horizontal Rear Wheel Adjustment

- **Goal** of moving the axle forward is to align the shoulder with the axle of the wheelchair.
- This will allow for a smoother, longer propulsion stroke on the hand rims and ultimately preserve the integrity of the shoulders.



Horizontal Adjustment – Push Length

- Reach back and contact rim
- Release rim in full elbow extension
- Measure the angle between the two
- The greater the degree of contact the fewer pushes it takes to cover the same distance

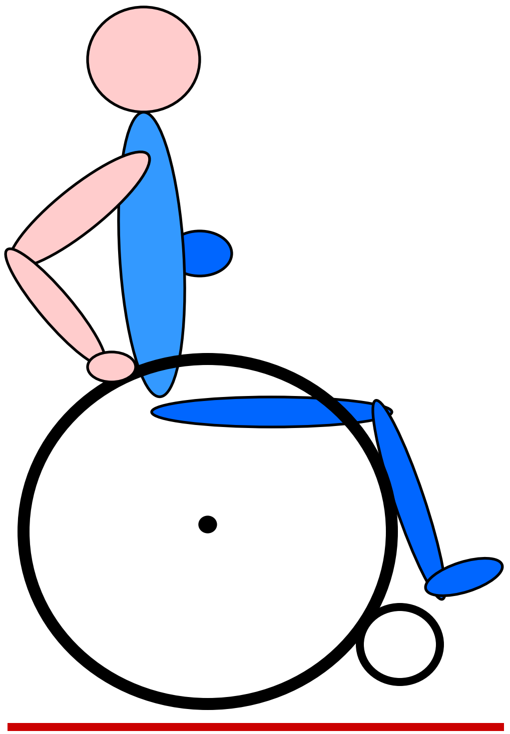
Horizontal Adjustment – Push Length

Proper UE Alignment Needed

Horizontal Wheel Position - Forward

Positions COG rearward

- ↓ weight on casters
- ↓ strength required
- ↓ work for UEs
- ↓ overall length/turning radius
- ↓ rearward stability
  - ? how much stability does your client need



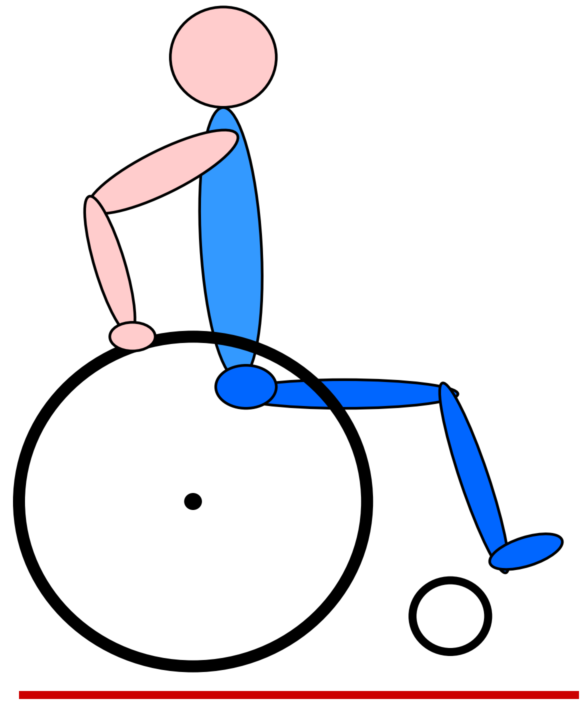
Affect on wheel access:

- Shoulder in more neutral position
- More efficient stroke
- Decrease risk of UE stress and damage

Horizontal Position - Rearward

Positions COG forward

- More weight on casters
- ↑ strength required
- ↑ work for UE muscles
- ↑ overall length/turning radius
- ↑ rearward stability



Affect on wheel access:

- Shoulder in excessive extension to initiate stroke
- Poor lever arm of force, inefficient stroke
- Increase risk of UE stress and damage

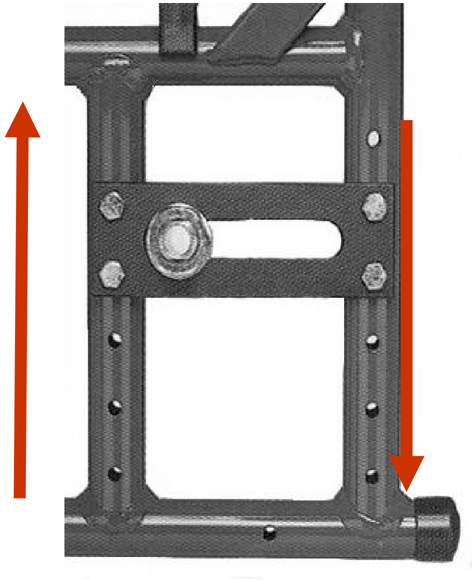
Rear Wheel Position Adjustability- Vertical

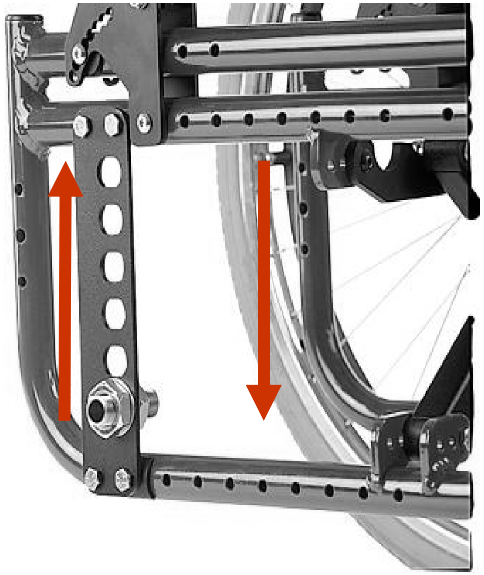
Definition	Benefits
Provides a means of adjustment of the vertical position of the rear wheels from the ground. Can be adjusted in the field without additional components unless supplied with the chair at initial issue. May require the use of tools. (May require a qualified technician to change.)	Allows wheels to move up/down on frame to affect access to pushrim which affects upper extremity position during propulsion. Lateral adjustment of the rear wheels also alters the seat to floor height which affects access to environments. This may allow independent transfers and/or safe transfers as well as foot propulsion. Rear seat height/front seat height differential creates seat inclination which affects postural stability.

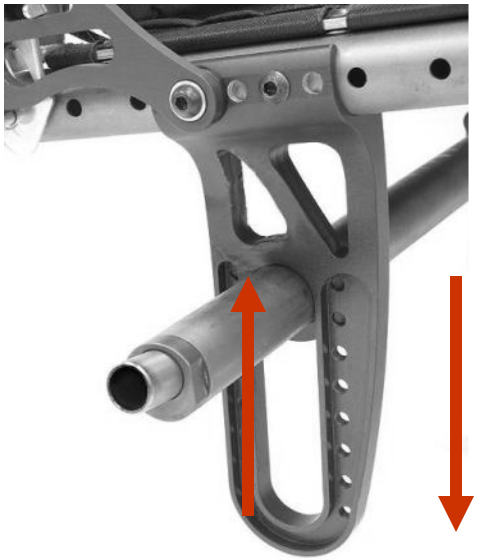
Vertical Rear Wheel Position

To change vertical wheel position:

- Move axle plate up/down on frame
- Move axle sleeve up/down in axle plate
- Position camber tube above/below frame or move up/down in axle plate



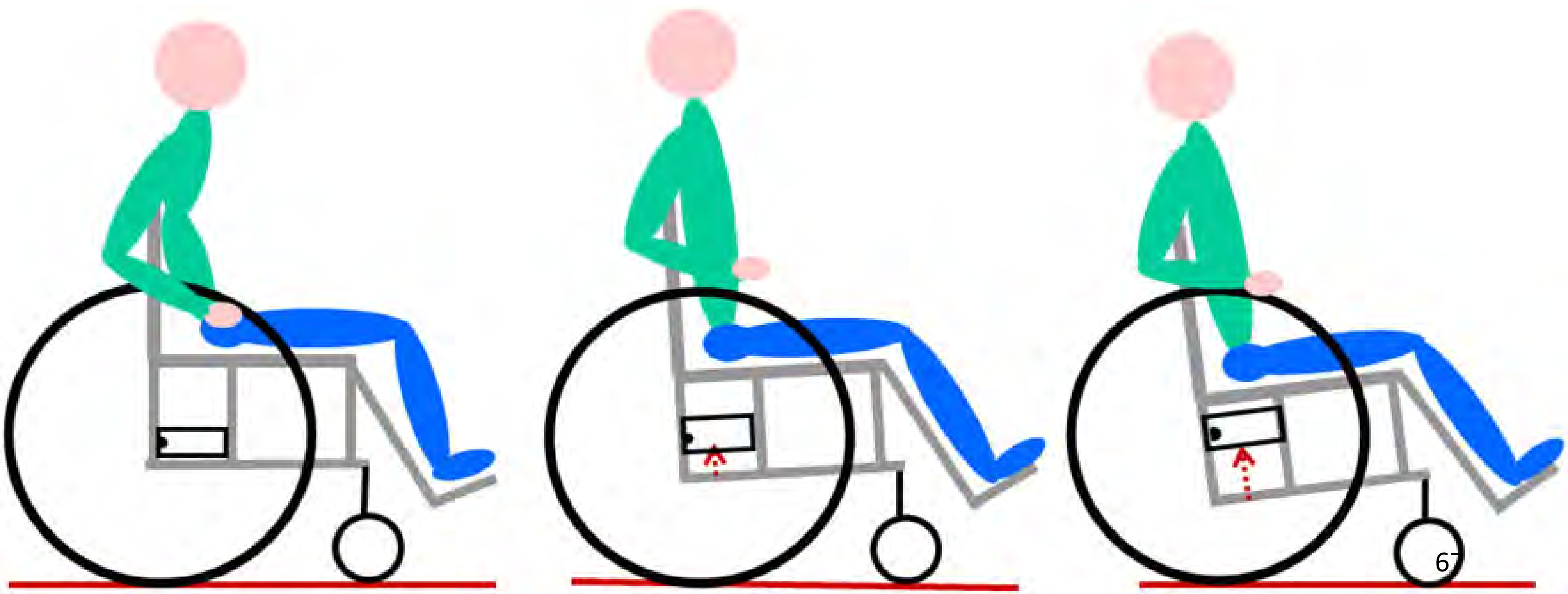




Remember impact to caster housing angle…

Vertical Adjustments

- Vertical adjustments:
  - Provides seat inclination (multiple degrees of fixed tilt) for posture and balance
  - Affect vertical wheel access
- Tailor the amount of inclination to each individual



Vertical Adjustment – Seat Incline

Front / Rear = Seat Incline

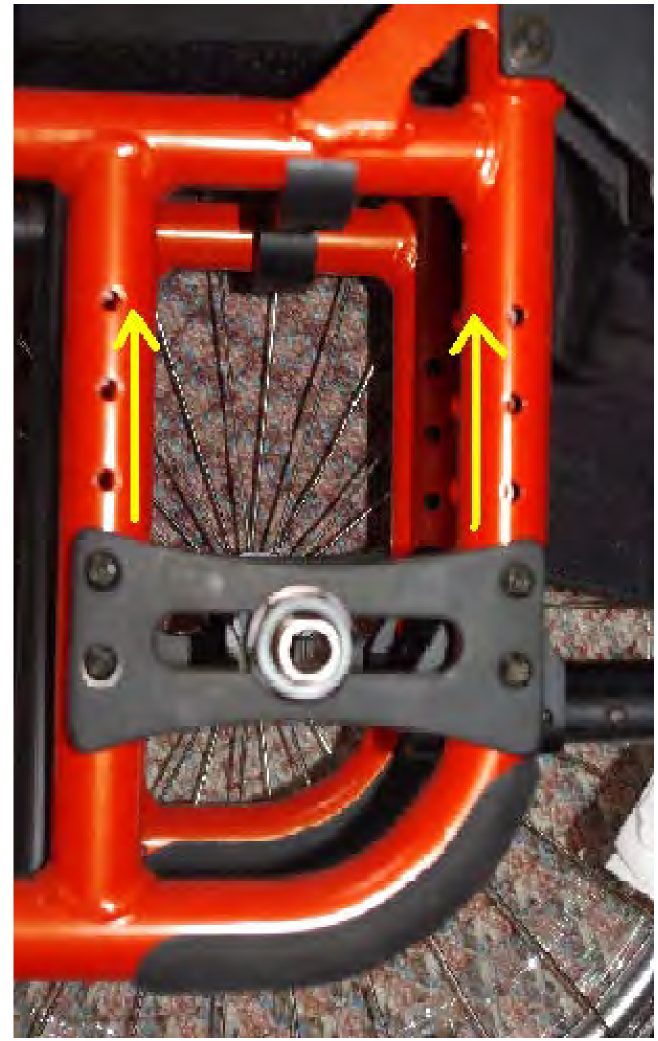
- Facilitates stabilization of the pelvis and trunk in combination with back height and seat to back angle

Caution

- May make transfers more difficult

Vertical adjustment

- **Goal** of aligning the vertical position of the axle is to set the upper extremities up in their most biomechanical advantageous position for propulsion.



Vertical Adjustment

- Seat too low
- Angle at 90°

- Seat just right
- Angle at 120°

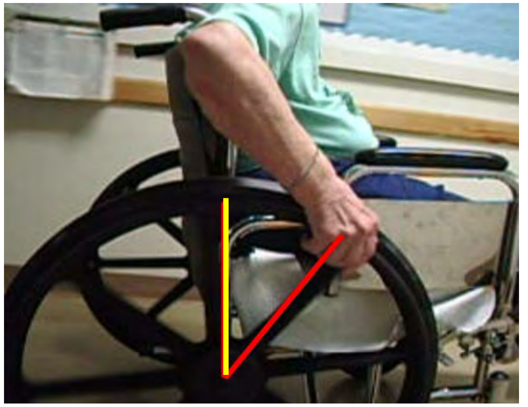
- Seat too high
- Angle at 135°

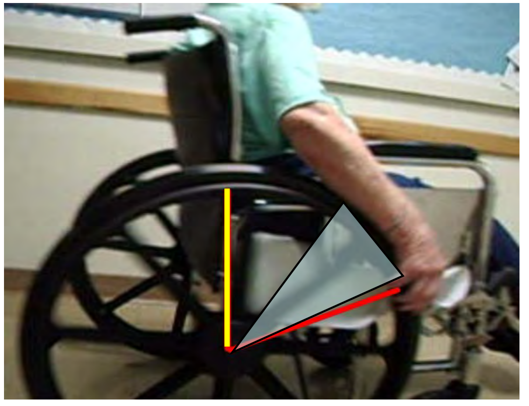
- With hand at top dead center of handrim, recommended elbow angle is between 100 and 120 degrees (van der Woulde, 1989)
- Strong clinical correlation with center of finger at center of axle

Information provided by Mark Schmeler, PhD, ORT/L, ATP

Vertical Adjustment- Low Seat

- Inability to reach back
  - Push handle interference
  - Limited shoulder extension & internal rotation
- Results in very small propulsion stroke
- Might 22" wheel or higher cushion help?





Rear Wheel Camber And Overall Width Capability

Definition

Frame design allows for various settings of the camber of the rear wheels (angle from the vertical) and for the distance between rear wheel and frame.

Benefits

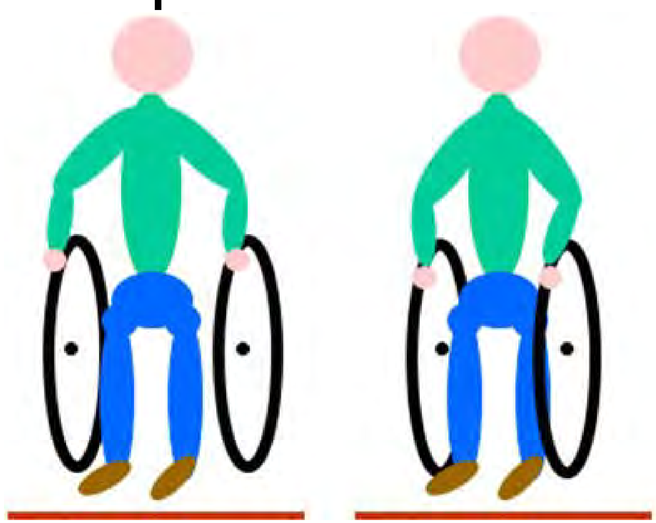
Adding camber can improve ease of turning, wheel access, efficiency of propulsion and side-to-side stability. The optimal camber for each client can change due to changes in function, overall chair size and/or environmental accessibility. Being able to set the distance between the rear wheel and the frame facilitates proper shoulder alignment with the rear wheel for propulsion. The rear wheel may also require lateral placement to accommodate doorways and other environmental barriers.

Rear Wheel Camber & Overall Width Adjustability Lateral

Definition	Benefits
Frame and/or rear wheel axle design allows for the adjustment of the camber of the rear wheels (angle from the vertical) and lateral distance between rear wheel and frame after the wheelchair is delivered without additional components.	Adjustment in camber or lateral rear wheel placement are needed to accommodate changes in environments, improved wheelchair skills, weight gain or loss, or the addition of components that are attached to the seat frame.

Lateral Adjustments

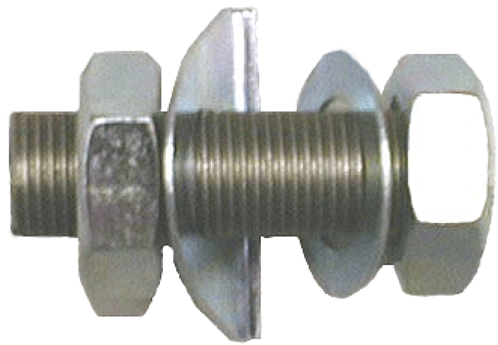
- Lateral adjustments provide:
  - Improved wheel access
  - Appropriate overall width
- Camber provides:
  - Increased efficiency of propulsion and turning
  - Improved wheel access

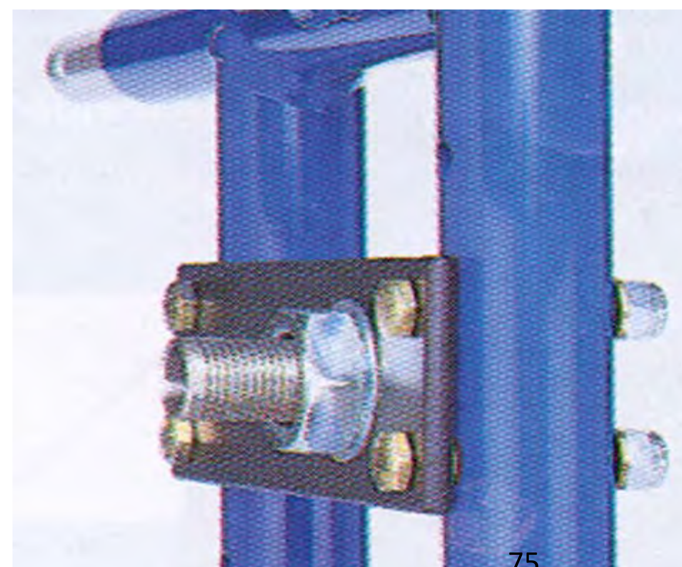


Lateral Wheel Position

To change lateral wheel position:

- Thread axle sleeve in or out





Lateral Wheel Position - Camber

Camber provides:

- ↑ lateral stability
- ↑ efficiency of turns/propulsion
- ↑ wheel access
- ↑ overall width at base

Change camber by:

- Axle plate – add/subtract spacers
- Camber tube - change tube
- Dual camber axle – put wheel into other axle sleeve

Lateral Wheel Position

Why do clients have poor lateral access?

- **Pediatrics** – small seating on wider chair for growth
  - Wheels too far away for efficient propulsion
  - Infrequent use of camber
  - *Consider* how much growth is really necessary
  - *Consider* camber
- **Elderly**- in standard width chairs - too wide
  - *Consider* more appropriate width chair
- **Bariatric** – wide chair to accommodate hip width
  - **Sleeve** wheels in if possible
  - **Add** camber if possible – often challenging

Lateral Wheel Position

Wheels further from frame

- Poor UE position
- Overall width increased
- Improved lateral stability?

- Accommodates more camber
- Accommodates user growth
- Accommodates hardware

Lateral Wheel Position

Best to have wheels as close to user as possible

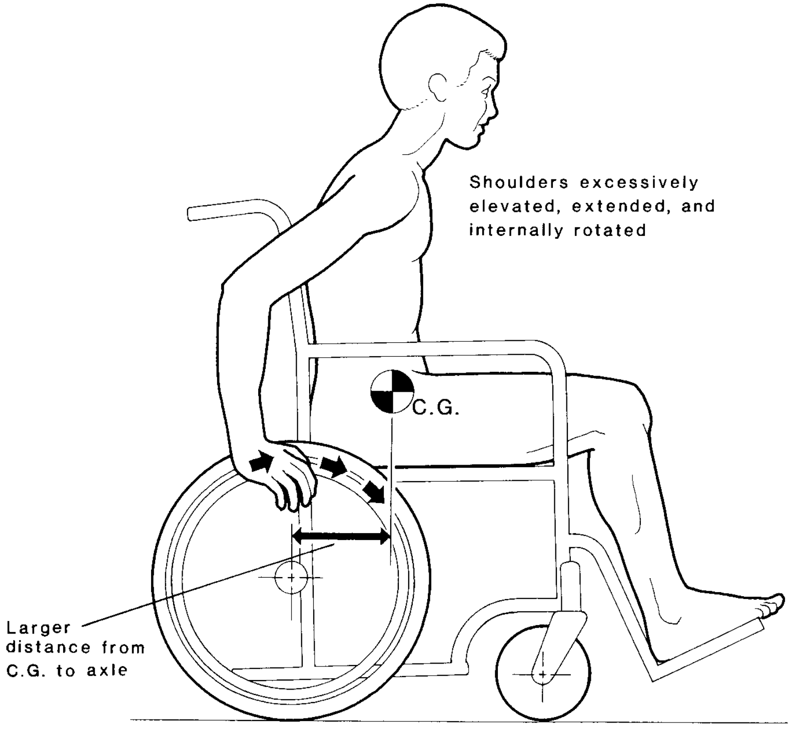
Optimal Rear Wheel Access

- Tip of middle finger at hub
- 100-120° of elbow flexion at top of push cycle
- 70-80% weight over rear wheels
- Good lateral access/camber

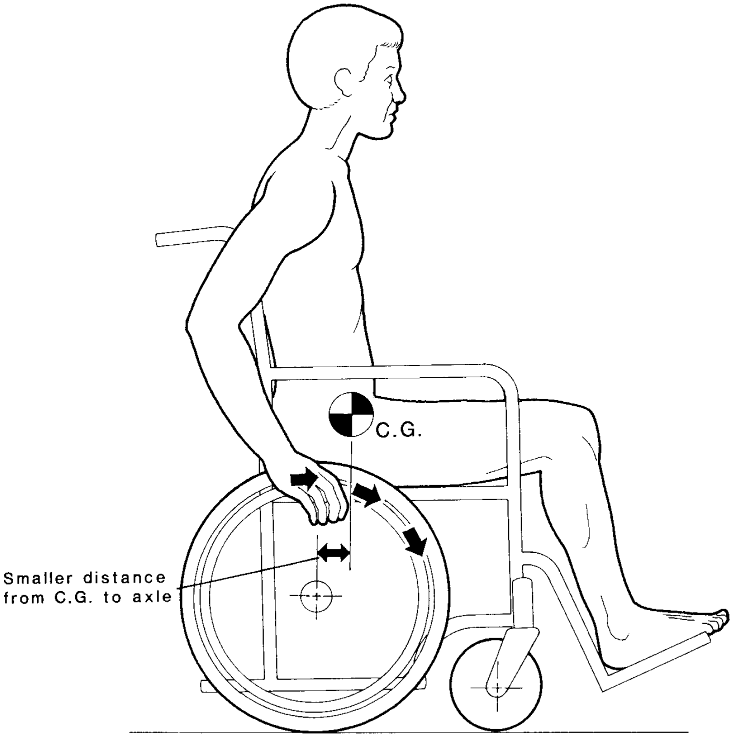
Access to Handrims

- Axle position and seat height impact access to handrims

To achieve good stroke, must extend and int rotate shoulder



Better stroke without hard-to-achieve ROM



Trunk Movement

- Increases propulsion stroke
  - And permits added torque
- Increases recovery cycle
- Forward trunk during stroke
  - ↑ stability especially on inclines
  - ↓ stability when hitting obstacles
- Probably not for all situations
- Can be a sign of fatigue and compensation of poor UE actions

Forward axle & proper seated height

- Arm better able to apply torque
  - Able to reach past peak
    - less extreme shoulder ROM required
  - Able to reach fwd
- Larger propulsion stroke

Propulsion by C5/6 SCI

Optimal Configuration Allows
Marginal Propellers to be Functional

Product Characteristic Definition List

Description	Definition
Manual Wheelchair	A medical device registered with the FDA under the following product classifications: Regulation Numbers, 890.3100, 890.3850, 890.3880 and/or product codes, INM, IOP,IQC,LBE.
Frame Depth	The horizontal measurement of the length of the frame between the attaching point of the caster stem and the attaching point of the rear wheels. If the chair offers adjustable rear wheel position and/or adjustable caster mounting, measurement must be from the most rearward position. Changes in this dimension results in variation of the distance between the back canes and the footrests.
Seat Depth Adjustability	Provides a means of adjustment of seat depth through forward extension of seat rail or equivalent. (May require a qualified technician to change).
Seat Frame Depth Adjustability	Provides a means of adjustment of seat depth through adjustment of the structural components of the frame without additional components unless supplied with the chair at initial issue. Changes in this dimension result in variation of the distance between the back canes and the footrests. May require the use of tools. (May require a qualified technician to change).
Seat Width	The horizontal measurement across the seat frame from one seat rail to the other.
Seat Frame Width Adjustability	Allows for adjustment of seat/frame width by adjustment of the structural components of the frame and/or is offered with at least one growth adjustment kit at no charge for components. May require the use of tools. (May require a qualified technician to change.)
Seat Frame Angle (Inclination) Capability	The angle of the seat relative to the horizontal plane. The value indicates the minimum angular capabablity available.
Seat Frame Angle (Inclination) Adjustability	Provide a means to adjust the seat angle relative to the horizontal plane without additional components unless supplied with the chair at initial issue. May require the use of tools and must not effect the perpendicular alignment of the caster housing. (May require a qualified technician to change.)
Seat to Back Angle	The angle of the back canes relative to the seat
Seat To Back Angle Adjustability	Provides a means to adjust the angle of the back relative to the seat without affecting the seat angle relative to the horizontal and without additional components unless supplied with the chair at initial issue . May require the use of tools. (May require a qualified technician to change.)
Angle for Removable Footrest or Front Frame Member	Provides a specific angle of the footrest hanger relative to the seat surface
Back Height	The vertical measurement of the back surface from the seat rail or horizontal seat frame to the top of the back upholstery
Back Height Adjustment	Provides a means of changing the back height by adjustment of the structural components of the frame without additional components unless supplied with the chair at initial issue. May require the use of tools. (May require a qualified technician to change.)
Seat to Floor Height	The vertical measurement from the floor to the seat surface
Rear Wheel Position (Horizontal)	The horizontal position of the rear wheels from the plane of the rear frame
Rear Wheel Position Adjustability (horizontal)	Provides a means of adjustment of the horizontal position of the rear wheels from the plane of the rear frame at the intersection of the vertical plane of the axle, forward in a maximum of 1/2" increments. Can be adjusted in the field without additional components unless supplied with the chair at initial issue. May require the use of tools. (May require a qualified technician to change.)
Rear Wheel Camber And Overall Width Capability (Lateral)	Frame design allows for the adjustment of the camber of the rear wheels (angle from the vertical) and for the distance between rear wheel and frame.
Tilt In Space	Provides a means for frequent repositioning of the angular position of the seat and back assembly relative to the horizontal plane. This adjustment must be achievable by users or caregivers frequently and without tools.
Tilt in Space Range	The degrees of adjustment of the angular position of the seat frame relative to the horizontal plane for tilt in space wheelchairs.

PDAC K0009 Product List

Technology Type	Manufacturer	Model	Model Number	Date of Launch	Date of Code Verification	DMEC System Comments	MSRP- Date of Pricing	Aggregate units sold in Category
Bariatric with Rear Axle adjustment	PDG PRODUCT DESIGN GROUP INC	ECLIPSE 600		6/19/05	7/15/1997		$2,600 - Jan 2013	
Bariatric with Rear Axle adjustment	SUNRISE MEDICAL (US) LLC	QUICKIE M6		10/1/00	10/16/2001		$2,895 - Oct2000	
Custom "made-to-measure" MWC	COLOURS 'N MOTION INC	COLOURS 'N MOTION			3/26/2003			
Custom "made-to-measure" MWC	COLOURS 'N MOTION INC	ZEPHYR			3/26/2003			
Custom "made-to-measure" MWC	INVACARE CORP	TOP END CROSSFIRE TITANIUM	CRFTi	11/1/06	11/13/2006	K0009	$3,114.00	
Custom "made-to-measure" MWC	INVACARE CORP	TOP END TERMINATOR TITANIUM	TEDTI	11/1/98	7/8/2005	K0009	$3,218.00	
Custom "made-to-measure" MWC	INVACARE CORP	TOP END TERMINATOR TITANIUM WITH HEAVY DUTY OPTION	TEDTI w/TED61 option	11/1/98	7/8/2005	K0009	$3,218.00	
Custom "made-to-measure" MWC	SUNRISE MEDICAL (US) LLC	QUICKIE Q7 ACTIVE RIGID	186WM61	8/24 2010	,		$2,725 Aug - 2010	
Custom "made-to-measure" MWC	TILITE	TILITE TR	TRFS1	5/1/99	12/21/2005	USE K0009 WHEN PROVIDED WITH A SEAT WIDTH AND SEAT DEPTH OF 15" OR GREATER. USE E1229 WHEN PROVIDED WITH A SEAT WIDTH AND SEAT DEPTH LESS THAN 15".	$3,195 - 7/1/2012	
Custom "made-to-measure" MWC	TILITE	TILITE TX	TXS1	5/1/06	8/11/2006	WHEN PROVIDED WITH A SEAT WIDTH AND SEAT DEPTH OF 15 INCHES OR GREATER.	$3,295 - 7/1/2012	
Custom "made-to-measure" MWC	TILITE	TILITE ZR	Z2FS1	5/1/04	12/21/2005	USE K0009 WHEN PROVIDED WITH A SEAT WIDTH AND SEAT DEPTH OF 15" OR GREATER. USE E1229 WHEN PROVIDED WITH A SEAT WIDTH AND SEAT DEPTH LESS THAN 15".	$3,195 - 7/1/2012	
Custom "made-to-measure" MWC	TILITE	TILITE ZRA	Z2FS2	6/1/03	12/21/2005	USE K0009 WHEN PROVIDED WITH A SEAT WIDTH AND SEAT DEPTH OF 15" OR GREATER. USE E1229 WHEN PROVIDED WITH A SEAT WIDTH AND SEAT DEPTH LESS THAN 15".	$2,895 - 7/1/2012	
Positioning tilt-in-space <45 degrees	PDG PRODUCT DESIGN GROUP INC	BENTLEY MANUAL TILT WHEELCHAIR		6/18/05	4/14/2006	PREVIOUSLY NAMED BENTLEY LONG AND SHORT FRAME.	$2,895 - Jan 2013	
Positioning tilt-in-space <45 degrees	PDG PRODUCT DESIGN GROUP INC	FUZE T20		6/29/05	1/11/2008		$2,895 - Jan 2013	
Positioning tilt-in-space <45 degrees	SUNRISE MEDICAL (US) LLC	QUICKIE IRIS & IRIS SE	183TA8	10/1/09	5/19/2010		$2,995 - Nov 2012 (Iris) $2,745 - Oct 2009 (SE)	
Positioning tilt-in-space <45 degrees	SUNRISE MEDICAL (US) LLC	QUICKIE IRIS & IRIS SE	183TA1	10/1/09	5/19/2010		$2,995 - Nov 2012 (Iris) $2,745 - Oct 2009 (SE)	
Standing Manual Wheelchair	LIFESTAND BY PERMOBIL	HELIUM	LSA	9/1/04	1/26/2010	K0009 + E2230	$10,995 - Jan 2012	
Standing Manual Wheelchair	PERMOBIL INC	HELIUM	LS	10/1/00	6/30/2011	K0009 + E2230	$9,995 - Jan 2012	
Standing Manual Wheelchair	PERMOBIL INC	HELIUM	LSE	10/1/00	6/30/2011	K0009 + E2230	$11,990 - Jan 2012	
Standing Manual Wheelchair	THE STANDING COMPANY	LIFESTAND			2/19/1999			
Standing Manual Wheelchair	THE STANDING COMPANY	SUPERSTAND STANDING WHEELCHAIR	SS-1		1/1/2009			
Product allows >45 degrees of tilt= E1161	MAPLE LEAF WHEELCHAIRS	SUPERTILT			11/17/1998			
	GUNNELL INC	MAC COMPLETE			10/31/1996			
	GUNNELL INC	MAC MOBILITY BASE			10/31/1996			
	MAPLE LEAF WHEELCHAIRS	MLT 700A			12/18/1998			
	MAPLE LEAF WHEELCHAIRS	MLTR 600			12/18/1998			
	Manufacturers did not provide data							

Comparison Matrix: Existing MWC HCPCS Codes to K0009 Products

Feature	Manual Wheelchair									
	K0001	K0002	K0003	K0004	K0005	K0006	K0007	Bariatric with Additional Features	Made to Measure	Positioning Tilt	Standing Manual WC
Frame Depth	No	No	No	No	Yes	No	No	Yes	Yes	Yes	Yes
Seat Depth Adjustability	No	No	No	Yes	No	No	No	No	No	Yes	Yes
Seat Frame Depth Adjustability	No	No	No	No	No	No	No	No	No	No	No
Seat Width	16", 18"	16",18"	16", 18"	16", 18"	12"-20" 1" increments	Varies with weight capacity	Varies with weight capacity	Varies with weight capacity	Specified on order form	Varies	Varies
Seat Frame Width Adjustability	No	No	No	No	No	No	No	No	No	Varies	No
Seat Frame Angle Capability	No	No	No	limited models	limited models	No	No	Yes	Yes	No	Yes
Seat Frame Angle Adjustability	No	No	No	limited models	limited models			limited models	Specified on order form	No	Yes
Seat to Back Angle	No	No	No	limited models	limited models	No	No	Yes	Varies	Yes	Yes
Seat To Back Angle Adjustability	No	No	No	limited models	limited models	No	No	limited models	Varies	Yes	Yes
Back Height	Fixed	Fixed	Fixed	limited models	Multiple Ranges	Fixed	Fixed	Varies	Varies	Varies	Varies
Back Height Adjustment	No	No	No		Available	No	No	Yes	Varies	Varies	Varies
Seat to Floor Height	19" or >	< 19"	≤19"	17"-19"	Multiple Ranges	Varies	Varies	Varies	Specified on order form	Varies	20"
Rear Wheel Position (Horizontal)	Fixed	Fixed	Fixed	Fixed	Yes	No	No	Adjustable	Specified on order form	Yes	Yes
Rear Wheel Position Adjustability (Horizontal)	No	No	No	No	Most models	No	No	2"	Available	Yes	Yes
Rear Wheel Camber And Overall Width (Lateral Adjustment) Capability	No	No	No	limited models	Most models	No	No	No camber, 1" lateral rear wheel adjustment	Limited models	No camber, lateral placement set by manufacturer	0 or 3 degrees of camber, lateral rear wheel placement is fixed
Adjustable Height Armrest	No	No	No	Yes	Yes	No	No	Yes	Available	Yes	Yes
Tilt In Space	NA	NA	NA	NA	NA	NA	NA	NA	NA	Yes	NA
Tilt in Space Range	NA	NA	NA	NA	NA	NA	NA	NA	NA	<45 degrees	NA
Chair Weight	>36	>36	34-36	<34	<30	NA	NA	NA	<20	NA	NA

Product Characteristics - Positioning Tilt In Space <45 Degrees MWC

Manufacturer	Chair	Seat depth adj.	Seat/Frame depth adj.	Seat/Frame angle adj.	Seat/Frame angle capability	Seat to back angle adj.	Tilt range	Back height adj	Floor to seat height adj.	Rear wheel position adj.	Rear camber & width capability	Width adj.	User Weight Limit	Std seat to floor height(s)	Std seat depth(s)	Std frame depth(s)	Std seat width(s)	Std back height(s)	Frame Warranty	Optional armrests	Optional footrests	Optional footplates	Excepts multiple rear wheels /tires	Excepts multiple castor wheels /tires
PDG PRODUCT DESIGN GROUP INC	BENTLEY MANUAL TILT WHEELCHAIR	16"-22"				90° - 122°	0° - 20°	No	13"-20"	Yes		No	350 lbs	13"-20"	16"-22"			25" and 31"	Lifetime	Yes	Yes	Yes	Yes	Yes
PDG PRODUCT DESIGN GROUP INC	FUZE T20	16"-20"				90° - 122°	0° - 20°	No	13"-20"	Yes		Yes	250 lbs	13"-20"	16"-20"			20" and 25"	Lifetime	Yes	Yes	Yes	Yes	Yes
SUNRISE MEDICAL (US) LLC	QUICKIE IRIS & IRIS SE					35 °	40 degrees	Yes	5.75"	7"			250 lbs.	12.5"-19.5"	14"-22"	1	14"-22"	15"-24"	Lifetime	Dual Post, DP-Ht Adj, DP Flip Back, DP Flip Back Ht Adj, Ht Adj Std/Low, Adj Locking Flip Up, Length Adj Locking Flip Up	70, 80 °,90 ° Swing In/Out Front Mount, 70, 80 °,90 ° HD Lift Off, 90o ELR, 60, 70 °,80 ° Swing In/Out Ext. Mount, ELR, ALR	Composite, Aluminum, Angle Adjustable, Platform	12", 16" 20", 22", 24" Mag, 24" Spoke Wheels	4"-1.5 Poly, 5"- 1.5 Poly, 6"-Pneu, Poly, 1.5 Poly, 8"- Poly, 1.5 Poly, 2 Pneu, Insert
SUNRISE MEDICAL (US) LLC	QUICKIE IRIS & IRIS SE					35 °	40 degrees	Yes	5.57"	7"			250 lbs.	12.5"-19.5"	14"-22"	1	14"-22"	15"-24"	Lifetime	Dual Post, DP-Ht Adj, DP Flip Back, DP Flip Back Ht Adj, Ht Adj Std/Low, Adj Locking Flip Up, Length Adj Locking Flip Up	70, 80 °,90 ° Swing In/Out Front Mount, 70, 80 °,90 ° HD Lift Off, 90o ELR, 60, 70 °,80 ° Swing In/Out Ext. Mount, ELR, ALR	Composite, Aluminum, Angle Adjustable, Platform	12", 16" 20", 22", 24" Mag, 24" Spoke Wheels	4"x1.5", 5"- 1.5 Poly, 6"-Pneu, Poly, 1.5 Poly, 8"- Poly, 1.5 Poly, 2 Pneu, Insert
Maple Leaf	Supertilt																							

CLINICAL INDICATIONS AND USER CHARACTERISTICS

POSITIONING TILT (<45 DEGREES) MANUAL WHEELCHAIRS

A positioning tilt in space manual wheelchair provides limited variable tilt in the seat frame (small degrees of changes in orientation in space achieved by changing the angle of the seat and back assembly relative to the horizontal plane). This provides a limited change in the user's position and orientation in space and can reduce the effects of gravity that are experienced in an upright posture. An individual who requires a positioning tilt in space manual wheelchair uses the wheelchair for his/her primary means of mobility and is either dependent in mobility or is able to propel with the upper or lower extremities independently in environments of typical use to complete routine ADLs and IADLs. This individual requires frequent and variable, but limited seat tilt due to one or more of the following:

- Inability to maintain optimal pelvic, trunk and/or head posture without periodic gravity assisted positioning during prolonged sitting due to muscle weakness or paralysis, increased or decreased muscle tone, poor endurance, increased fatigue and/or cognitive impairment. Postural supports alone, such as an anterior pelvic support (pelvic positioning belt) and an anterior trunk support (chest harness) are not sufficient.
- Risk of physiological and functional complications resulting from postural deformities from prolonged upright sitting due to muscle weakness or paralysis, increased or decreased muscle tone, poor endurance, increased fatigue and/or cognitive impairment.
- Experiences functionally limiting pain with prolonged upright sitting that is managed with frequent limited periodic changes in seat tilt
- Inability to independently assume or maintain the variable postures that allow maximum upper extremity, visual and communication functions for participation in routine ADLs and IADLs
- Respiratory compromise requiring specific variable (tilted) positions for respiratory care and function
- Risk for aspiration or impaired digestive functioning requiring specific variable (tilted) positions for safe swallowing, safe oral or enteral feeding, saliva management, digestion and/or access to medical devices and stomas
- The need for <u>independent</u> periodic and frequent operation of the tilt mechanism to minimize the caregiver assistance required to manage pain, postural collapse and/or fatigue from poor tolerance to upright sitting

PDG Fuze T20- Positioning Tilt <45 Degrees Case Example

Erin Bischofberger, PT, DPT, ATP
Methodist Rehabilitation Center
Seating and Wheeled Mobility Clinic
Jackson, MS

"Richard" is a 36 year old male with a diagnosis of Huntington's chorea. He is 5'10 and weighs 138 pounds. He was initially admitted to the hospital with diarrhea, however, a fall while in the hospital resulted in a subdural hematoma that required surgery. The extended hospital stay caused a significant decrease in his strength.

Richard lives with his mother and sister. Someone is with him at all times during the day. He lives in a house with one step for entrance. No ramps are in place. The doorways throughout the home are 32 inches wide. His family has a 2008 Ford Focus that will be the primary mode of transportation for Richard and his wheelchair.

Prior to his hospital stay, Richard was ambulating throughout the home with assistance from his sister and mother and did not use a wheelchair, however, this is no longer a safe option. He is no longer able to ambulate safely due to his decrease in strength as well as his uncontrolled and uncoordinated movements. Richard was provided with a K0004 Quickie Breezy manual wheelchair as a loaner when he was discharged from the hospital, however, he has been unable to use it independently at home. He cannot maintain pelvic position and slides forward, nearly sliding to the floor due to his uncontrolled movements.

Richard requires minimal assistance to transfer to same level surfaces, moderate assistance for transfers to the bed and to a car, and maximal to total assistance with transfers on and off the floor. He needs maximal assistance or is dependent with self-care, dressing and bathing. He is able to feed himself with minimal assistance. His difficulty with the various tasks results from his uncontrolled movements due to his Huntington's chorea. Throughout the evaluation Richard had very large uncontrolled movements of bilateral upper extremities and lower extremities.

Richard did not have any significant postural deformities. He had good head control, but poor sitting balance and poor trunk control. Passive range of motion was normal throughout. Richard had good (4/5) strength in both upper extremities and both lower extremities but had decreased coordination and great difficulty controlling his movements. He demonstrated slightly better control of his lower extremities compared to his upper extremities.

Richard's anatomical measurements taken in a short seated position at the edge of the mat were as follows: hip width was 15", thigh length was 19" on left and 19.5" on right, lower leg length was 20" bilaterally and shoulder height was 23" bilaterally.

The primary goal for Richard was independent wheelchair mobility using his lower extremities for propulsion, since this was where he had the better motor control. In order to effectively use his lower extremities, however, he needed gravity-assisted positioning and support to improve his trunk stability. He also requires a seat to floor height low enough to allow his feet to reach the floor. He was unable to propel a standard manual wheelchair or a recliner wheelchair due to inability to reach the floor with his feet and due to instability of his trunk from his uncontrolled movements. He was unable to maintain good pelvic position and was constantly sliding forward in the seat despite the use of pelvic positioning belts. A standard tilt-in-space provided the required gravity assisted position, but did not allow his feet to reach the floor when in a tilted position due to the tilt mechanism design. In addition, he did not require the range of tilt provided by a full tilt. A custom ultra-light manual wheelchair would also not work. When configured in an upright orientation, Richard would slide forward when propelling with this feet due to his postural instability and uncontrolled movements. If the frame were configured in a fixed tilt for postural support, he would have difficulty reaching the floor to propel and would be unable to perform sit to stand transfers out of the chair. A power wheelchair is not an option for Richard as he does not have enough control or coordination of any extremity to operate a joystick or any other drive mechanism including head array, sip –n-puff, mini-proportional joystick or any foot switches.

The only wheelchair that provided the appropriate postural support and allowed independent propulsion was the PDG Fuze T20. In this wheelchair, Richard could sit in a minimally tilted position, which significantly improved his posture and stability, but he could also achieve a more level (upright) orientation for safe sit to stand transfers. In addition, Richard was able to achieve independent foot propulsion while in a tilt position due to the unique tilt mechanism of the PDG Fuze T20. When the wheelchair is tilted the rear portion of the wheelchair <u>lowers</u> to create the tilt but the front stays at the same height. Richard was able to achieve and maintain a stable trunk position while also reaching the ground with his feet for propulsion. Using the PDG Fuze T20 manual tilt wheelchair, Richard was able to use his lower extremities in a controlled manner to propel from point A to point B over smooth and carpeted surfaces and to navigate in open and crowded areas independently.

The PDG Fuze T20 manual tilt wheelchair improved Richard's overall mobility function, improved his posture (both static and dynamic) and ensured his safety while in the wheelchair even with the uncontrolled movements of his upper extremities. It also decreased the likelihood of skin breakdown from shear forces since he was no longer sliding in the wheelchair. Without this wheelchair, Richard would be dependent for his mobility needs and would also be at risk for skin breakdown and from injury due to falls from the wheelchair.

Invacare Compass - Positioning Tilt <45 Degrees Case Example

Jill Sparacio, OTR/L, ATP/SMS, ABDA
Sparacio Consulting Services
Downers Grove, IL

"Patrick" is a 28-year-old male with diagnoses of cerebral palsy, Angelman's Syndrome, cerebellar ataxia, intellectual disability, spastic quadriparesis, osteopenia, oral/motor dysfunction with g-tube and hypertension. Patrick resides in a skilled nursing facility for developmentally disabled and medically fragile children and adults. He is non-ambulatory, requires maximum assist of one for stand pivot transfers and is dependent for long distance mobility. Patrick is presently using a standard (K0001) manual wheelchair that does not offer good fit or postural support. With the design and configuration of his current mobility system he has difficulty self propelling with his upper extremities. Even still, he is determined to self propel short distances within his residence, moving from one room to another to participate in mobility related activities of daily living as well as recreation and leisure activities. Patrick attends a developmental training program that is located on the same campus however due to the distance and his difficulty self propelling he remains dependent in mobility to get there.

A typical day for Patrick includes participating in usual morning activities of daily living. Although he can assist with grooming, dressing, toileting etc., Patrick requires moderate to maximal assistance from one person due to his imbalanced muscle tone, ataxia and intellectual disability. Patrick receives his nutrition via g-tube, receiving nothing by mouth. At his developmental training program, Patrick participates in learning prevocational tasks, positioning for time out of his wheelchair (sidelying, modified prone), toileting and g-tube feeding activities. While there, he struggles to self propel from one room to another using his upper extremities, as directed by staff. This is laborious and uses a significant amount of energy in his current equipment. Once he returns to his residence, Patrick participates in positioning, recreation and leisure activities as well as routine self care tasks to prepare for bed. He attempts to self-propel around his residence as well, but can do so only with significant effort and extra time. He often needs some assistance from the staff as he fatigues. It has been important to Patrick and staff that he participates as much as possible in his daily routine. Due to the extent of his limitations, self propelling remains one of the few tasks he could complete safely with supervision and verbal prompts alone given the appropriate system.

When seated on the edge of a mat, Patrick presents with a fixed posterior pelvic tilt and kyphosis resulting in rounded shoulders and a flexed head and neck posture. He has a left pelvic obliquity (left side of pelvis lower than right) and C curve scoliosis with convexity left at the mid thoracic level. He tends to sit with his lower extremities abducted and externally rotated in what appears to be an attempt to gain the greatest degree of postural stability. Patrick is limited to 85 degrees of hip flexion bilaterally due to tightness. With his hips flexed to 85 degrees he only has knee extension to 110 degrees bilaterally due to tight hamstrings that limit knee extension. He tends to hold his feet in a plantarflexed position and is unable to attain a neutral dorsiflexed position passively due to contracture. Patrick does not have functional movement of his lower extremities to assist with LE propulsion. He is also unable to get his feet flat on the floor due to his plantarflexion contractures. Patrick has good gross motor movements of his upper extremities and is successfully able to use his arms for self propelling his wheelchair. However due to his ataxia, hand function for fine motor activities and motor control/coordination are both limited.

As a result of his kyphotic posture Patrick's eyes are directed downward when sitting in his wheelchair, which limits his ability to visually attend and interact with others. In order to "look up", he must position his neck in extreme cervical hyperextension to attain a neutral horizontal gaze position. This is unsustainable due to discomfort, effort and fatigue.

Patrick's present equipment is a standard (K0001) folding wheelchair with fixed rear axles, 90 degree seat to back angle and 60 degree swing away footrests with standard footplates. He sits in planar seating with lateral thoracic pads, lateral thigh pads, a small headrest, H style chest harness, anterior pelvic support and shoe holders. The difficulties with this system include the following:

1. 90 degree seat to back angle does not accommodate his limited hip flexion of 85 degrees. He is forced to slide his hips and pelvis forward on the seat to gain a more open angle, which exaggerates his posterior pelvic tilt and thoracic kyphosis. As his weight shifts further forward on the base it becomes more difficult for him to access the rear wheels for effective self propulsion.
2. The 60 degree footrest hangers exceed his available range of knee flexion which is limited by his hamstring tightness. When his feet are placed on the footplates, his hamstrings are stretched beyond their limit and the pelvis is pulled forward, further compromising his seated posture and ability to access the rear wheels for self propulsion.
3. Patrick's slumped kyphotic posture positions his shoulders forward, making it even more difficult to reach the fixed rear wheel on the K0001 MWC for self propulsion. The wheels are too far behind his shoulders.
4. Due to Patrick's poor seated posture and lack of postural support Patrick tends to assume a position of LE abduction to widen his base of support and increase his postural stability.

The goals identified during the evaluation are as follows:

1. Patrick will be able to use his upper extremities for safe and efficient self propulsion from one location to another with verbal prompting only.
2. Patrick will be able to achieve and maintain the most neutral and upright sitting posture possible without further progression of his fixed deformities and will be able to engage in routine functional activities.
3. Patrick will be able to maintain a neutral visual gaze to engage in communication and activities.
4. Patrick will be able to safely and efficiently participate in functional tasks (self care, vocational, social/recreational) with the least amount of assistance necessary.

Equipment trials were completed in three different mobility bases as follows:

1. Trial in a full tilt in space (greater than 45 degrees) with adjustable seat to back angle. The tilt in space angle provided the gravity-assisted postural support and re-orientation needed for improved upper trunk and head positioning to provide a horizontal eye gaze. The open seat to

back accommodated the hip contractures. However, Patrick had difficulty gaining sufficient access to the rear wheels for self propelling. In addition, the overall weight of the wheelchair and seating system resulted in rapid fatigue when attempting to self propel. And Patrick did not require the full range of tilt that was on this base.

2. Trial in a non-tilting base with seat to back angle adjustability. The open seat to back angle accommodated Patrick's limited hip flexion and posterior pelvic tilt, but the vertical orientation on the non-tilt base did not sufficiently accommodate his fixed kyphosis and cervical flexion. Tilt is needed to provide gravity-assisted support to prevent further sliding and to enable a horizontal visual gaze. .
3. Trial in a fixed tilt frame with seat to back angle adjustability. The open seat to back accommodated the hip contractures. The fixed tilt provided the gravity assist for posture and the re-orientation in space for horizontal eye gaze. However, it significantly interfered with his stand pivot transfers since the seat to floor height was now higher.
4. Trial in a positional tilt with less than 45 degrees of tilt and seat to back angle adjustability (Quickie IRIS SE with limited tilt). The open seat to back angle accommodated Patrick's hip contracture and fixed posterior pelvic tilt. Tilting the seat 15-20 degrees provided the gravity assisted positioning required to prevent further sliding and allow a functional visual gaze. The frame could also be "un-tilted" to neutral to provide a lower and more level seat for transfers and other ADLs. By providing sufficient postural support Patrick could attain and maintain a hands free posture. This allowed him to be able to use his upper extremities to access the rear wheels. In addition, the rear wheels could be brought forward on the frame to further improve access. Front hangers with a tighter front hanger and adjustable angle footplates accommodated his knee flexion contractures (tight hamstrings) and accommodated/supported his plantar flexion contractures without losing his postural position. Patrick was able to propel with much less effort and in a much timelier manner while still maintaining his best posture and a level eye gaze. Attempts at self propelling were successful, and he was able to navigate throughout his residence and training program.

Final Equipment Recommendations for Patrick included:

1. Mobility Base: Quickie IRIS SE with 40 degrees of tilt, semi-adjustable rear axles, adjustable seat to back angle set at 95 degrees, 70 degree hangers, angle adjustable footplates.
2. Seating System: Invacare Contour U seating to accommodate fixed pelvic obliquity and posterior pelvic tilt, thoracic kyphosis and scoliosis ; small headrest, H style chest harness, 1-1/" dual pull anterior pelvic support.

It should also be noted that a power trial was completed during the evaluation process. This was done to determine if Patrick could experience greater independence in mobility and if the ease of power mobility would result in less asymmetry and stress on his body. Due to Patrick's intellectual disability, power was ruled out as a safe option.

Since the evaluation Patrick has received the recommended MWC and seating system. His new system has allowed Patrick to move about his residence as needed. Although he requires assistance of one for transfers, set up and supervision, once in his MWC he is able to move safely around his environments without caregiver assistance and he is able to wield some control over his environment without compromising his physical status.

Positioning Tilt < 45 Degrees MWC – Evidence Summary

As described in the "Clinical Indications and User Characteristics," positional tilt wheelchair systems provide seat tilt of less than 45 degrees. Some models also offer limited seat to back angle adjustability to provide a fixed back recline of 30 degrees or less. Some products in this category offer tilt control mechanisms positioned such that the wheelchair occupant is able to access the controls for independent activation of the tilt. This may be critical if the clinical indication addressed is the need for management of pain or discomfort as well as facilitation of independent mobility. Evidence related to the use of positional tilt systems is grouped in three main topic areas: effects of positional tilt on propulsion characteristics, effects of positional tilt on soft tissue and pressure management, and the general effects of these systems on people who use them. A significant body of evidence exists related to tilt (or "tilt-in-space") technologies in general, however the studies represented in this summary focus on tilted positions less than 45 degrees, referred to as positional tilt systems.

In their study of the effects of small degrees of system tilt on propulsion, researchers discovered a beneficial increase (10%) in efficiency of propulsion for a group of older adults using a 10 degree system tilt (Aissaoui, Arabi, Lacoste, Zalzal, & Dansereau, 2002). This biomechanical efficiency was more sensitive to the system tilt parameter than to a simpler back angle adjustment resulting in limited recline. This is a very important finding for older adults, many of whom benefit from positional tilt systems for this enhancement in mobility, as well as for postural support and pain management. Desroches et al. (2006) studied the effects of positional tilt on shoulder joint loads during propulsion. This research further confirmed that as long as the position of the shoulder relative to the wheelchair axle is held constant (in both vertical and horizontal locations), small changes in either tilt or recline do not increase shoulder joint loads during wheelchair propulsion. The implication of this research is that positional tilt systems may be used for comfort, posture management, or some pressure management without interfering with independent propulsion. This is an important characteristic as many wheelchairs designed with full tilt systems are not intended to be self propelled by the wheelchair occupant, but many positional tilt systems maintain the features required for independent mobility.

Researchers have used measurement of two main pressure ulcer risk factors – interface pressure and blood flow in tissues – in a variety of tilted or combination tilted and reclined positions using positioning technologies. Although the general consensus among researchers is that tilts larger than 45 degrees are optimal for off loading of interface pressures, this research has indicated that small changes in angle of tilt achieve at least some pressure reduction under the ischial tuberosities and a 30 degree tilt may begin to reduce pressure under the sacrum (Giesbrecht, Ethans, & Staley, 2011). Smaller angles of tilt (25 or 35 degrees) may be particularly effective at increasing blood flow under the ischial tuberosities when combined with 10 – 30 degrees of recline (or a 100 or 120 degree seat to back angle), which may be achieved either through a variable recline system or through a fixed seat to back support angle of 100 or 120 degrees (Jan, Jones, Rabadi, Foreman, & Thiessen, 2010). Two additional studies (Sonenblum & Sprigle, 2011; Sprigle, Maurer, & Soneblum, 2010) also recommend tilting a system maximally for pressure redistibution purposes, but acknowledge that smaller angles of tilt may provide some benefit in the area of pressure re-distribution and increasing blood flow under the primary weight bearing surfaces.

Positional tilt systems may also be useful for their effects on postural control or upper extremity function. In a review of the evidence related to the impact of positional tilt on upper extremity function, Stavness (2006) concluded that a seat tilt that is neutral or slightly anterior (small angle) is useful for facilitating upper extremity function in children with cerebral palsy (CP). Individuals with neuromuscular conditions like CP may benefit from positional tilt systems to optimize their postural control through the use of gravity assisted positioning, maximize their comfort and facilitate control of their upper extremities while sitting in their wheelchairs. They also benefit from small incremental changes in tilt throughout the day to allow them periods of rest and pressure re-distribution. In a qualitative study of individuals with multiple sclerosis, several benefits of positional tilt were highlighted, including increased comfort, improved postural support and control through gravity assisted positioning, enhanced sitting stability, improved pressure management, and ability to rest frequently while out of bed, which minimizes transfers and extends the number of hours that subjects could be out of bed (Dewey, Rice-Oxley, & Dean, 2004). The only difficulties reported by users of positional tilt systems in this study were issues with bulkiness or reduced maneuverability of the devices themselves and difficulties with transportation of the systems in the community. Overall, participants in this study reported general satisfaction with these devices and a higher percentage of users of positional tilt systems were satisfied (6 out of 7) compared to a control group using conventional wheelchairs (8 out of 16). Both of these studies highlight the function and comfort benefits of positional tilt systems.

Positioning Tilt In Space <45 Degrees Manual Wheelchair References:

Aissaoui, R., Arabi, H., Lacoste, M., Zalzal, V., & Dansereau, J. (2002). Biomechanics of manual wheelchair propulsion in elderly: system tilt and back recline angles. *Am J Phys Med Rehabil, 81*(2), 94-100.

Desroches, G., Aissaoui, R., & Bourbonnais, D. (2006). Effect of system tilt and seat-to-backrest angles on load sustained by shoulder during wheelchair propulsion. *J Rehabil Res Dev, 43*(7), 871-882.

Dewey, A., Rice-Oxley, M., & Dean, T. (2004). A qualitative study comparing the experiences of tilt-in-space wheelchair use and conventional wheelchair use by clients severely disabled with multiple sclerosis. *The British Journal of Occupational Therapy, 67*(2), 65-74.

Giesbrecht, E. M., Ethans, K. D., & Staley, D. (2011). Measuring the effect of incremental angles of wheelchair tilt on interface pressure among individuals with spinal cord injury. *Spinal Cord, 49*(7), 827-831. doi: sc2010194 [pii]10.1038/sc.2010.194

Jan, Y. K., Jones, M. A., Rabadi, M. H., Foreman, R. D., & Thiessen, A. (2010). Effect of wheelchair tilt-in-space and recline angles on skin perfusion over the ischial tuberosity in people with spinal cord injury. *Arch Phys Med Rehabil, 91*(11), 1758-1764. doi: S0003-9993(10)00628-3 [pii]10.1016/j.apmr.2010.07.227

Sonenblum, S. E., & Sprigle, S. H. (2011). The impact of tilting on blood flow and localized tissue loading. *J Tissue Viability, 20*(1), 3-13. doi: S0965-206X(10)00067-7 [pii]10.1016/j.jtv.2010.10.001

Sprigle, S., Maurer, C., & Soneblum, S. E. (2010). Load redistribution in variable position wheelchairs in people with spinal cord injury. *J Spinal Cord Med, 33*(1), 58-64.

Stavness, C. (2006). The effect of positioning for children with cerebral palsy on upper-extremity function: a review of the evidence. *Phys Occup Ther Pediatr, 26*(3), 39-53.

Product Characteristics - Made to Measure MWC

Manufacturer	Chair	Seat depth adj.	Seat/Frame depth adj.	Seat/Frame angle adj.	Seat/Frame angle capability	Seat to back angle adj.	Tilt range	Back height adj	Floor to seat height adj.	Rear wheel position adj.	Rear camber & width capability	Width adj.	User Weight Limit	Std seat to floor height(s)	Std seat depth(s)	Std frame depth(s)	Std seat width(s)	Std back height(s)	Frame Warranty	Optional armrests	Optional footrests	Optional footplates	Accepts multiple rear wheels /tires	Excepts multiple castor wheels /tires
COLOURS 'N MOTION INC	COLOURS 'N MOTION																							
COLOURS 'N MOTION INC	ZEPHYR																							
SUNRISE MEDICAL (US) LLC	QUICKIE Q7 ACTIVE RIGID				16 °	8°		4"		±1/2"	0°,3°,6° / 1"		265	16"-21"	12"-20"	12"20"	12"-20"	8"-19"	lifetime	single post height adj. 2 sizes, 4 style of armpads	5 types		Yes, 4 sizes, 6 types, 9 tires	Yes, 4 sizes, 7 types
TILITE	TILITE TR				17 °	21 °		≥3"		5"	12 ° 1.5"		265	15"-21"	12"-19"	12"-19"	12"-19"	8.5"-20.5"	lifetime	4 types; 12 total counting different sizes and heights	5 types	18 sizes/types	Yes. 8 wheels types; 23 wheel type/size combinations; multiple tire selections	yes. 17 caster type/size/tire combinations
TILITE	TILITE TX				11 °	20 °		≥4"		2.25"	4 ° 1.25"		250	15"-21"	14"-19"	14"-19"	14"-19"	12"-20"	lifetime	3 types; 9 total counting differrent sizes and heights	11 types	38 sizes/types	Yes. 7 wheel types; 21 wheel type/size combinations; multiple tire selections	yes. 16 caster type/size/tire combinations
TILITE	TILITE ZR				17 °	21 °		≥3"		2.25"	12 ° 1.25"		265	16"-21"	10"-19"	10"-19"	10"-19"	8.5"-20.5"	lifetime	2 types; 4 total counting different heights	5 types	19 sizes/types	Yes. 8 wheels types; 23 wheel type/size combinations; multiple tire selections	yes. 17 caster type/size/tire combinations
TILITE	TILITE ZRA				17 °	21 °		≥3"		6"	12 ° 1.25"		265	16"-21"	10"-19"	10"-19"	10"-19"	8.5"-20.5"	lifetime	4 types; 12 total counting different sizes and heights	5 types	19 sizes/types	Yes. 8 wheels types; 23 wheel type/size combinations; multiple tire selections	yes. 17 caster type/size/tire combinations
INVACARE CORP	TOP END CROSSFIRE TITANIUM				70, 75, 80, 85, 90	95, 90, 85, 80, 75		9-11" 10-14" 12-16" 14-18" 16-20" or Fixed		Active: 1.15-5.5" Extended: -2.25-2"	0 3 6 9 12		250lb	Front: 16-21" Rear: 14-21"	14 15 16 18 19 20	n/a	12 13 14 15 16 17 18 19 20	9-11" 10-14" 12-16" 14-18" 16-20" or Fixed	Limited lifetime	Yes	Yes	Yes	Yes	Yes
INVACARE CORP	TOP END TERMINATOR TITANIUM				70, 75, 80, 85, 90	95, 90, 85, 80, 75		9-11" 10-14" 12-16" 14-18" 16-20" or Fixed		Fixed	0 3 6 9 12		250lb	Front:17-21" Rear14.5-21"	14 15 16 18	n/a	12 13 14 15 16 17 18	9-11" 10-14" 12-16" 14-18" 16-20" or Fixed	Limited lifetime	Yes	Yes	Yes	Yes	Yes
INVACARE CORP	TOP END TERMINATOR TITANIUM WITH HEAVY DUTY OPTION				70, 75, 80, 85, 90	95, 90, 85, 80, 75		9-11" 10-14" 12-16" 14-18" 16-20" or Fixed		Fixed	0 3 6 9 12		400lb	Front:17-21" Rear14.5-21"	14 15 16 19	n/a	12 13 14 15 16 17 18	9-11" 10-14" 12-16" 14-18" 16-20" or Fixed	Limited lifetime	Yes	Yes	Yes	Yes	Yes

CLINICAL INDICATIONS AND USER CHARACTERISTICS

MADE TO MEASURE CUSTOM MANUAL WHEELCHAIRS

An individual who requires a made to measure manual wheelchair uses the wheelchair for his/her primary means of mobility and is able to propel independently in environments of typical use to complete routine ADLs and IADLs. This individual may have impairments that include but are not limited to upper extremity muscle weakness or paralysis, increased or decreased muscle tone, poor trunk stability and balance, decreased motor control, decreased endurance, decreased range of motion or contractures in the upper extremity(s), trunk, pelvis or neck, loss of limb(s) and/or pain. He/she requires a custom manufactured, custom designed frame with a combination of adjustable and/or custom configured features that cannot be achieved with an ultralight weight manual wheelchair (K0005) due to one or more of the following:

- Unable to attain/maintain stable and functional seated posture to complete routine ADLs and IADLs without the maximum degree of individualized and intimate fit of the wheelchair (similar to that provided by a custom orthosis)
- Cannot be accommodated in the seat and frame dimensions achievable on a K0005 due to atypical anthropometrics (e.g., atypical body dimensions, loss of limb or limbs, anatomical anomalies).
- Is unable to complete routine ADLs and IADLs due to upper extremity pain from overuse, repetitive strain injury, musculoskeletal injury or joint disease without the use of a custom specified ergonomic wheel position and/or frame configuration
- Is unable to access routine environments, surfaces, and objects within these environments for completion of routine ADLs and IADLs without the custom designed and configured wheelchair seat and frame
- Requires the maximum durability provided by a custom welded frame design with fewer frame components due to high activity level, uneven, rough environmental terrains, severe spasticity, and/or other factors that negatively affect the life-cycle of the wheelchair for that individual

A made to measure manual wheelchair is built to each individual's unique specifications and is designed to achieve as close as possible to ideal fit and functionality for the intended user. The combination of adjustable and/or custom features provide the specified ergonomic position that will maximize the efficiency of propulsion for that individual by decreasing the amount of force per stroke, decreasing stroke frequency, improving stroke pattern, allowing safe upper extremity position and decreasing rolling resistance. This will reduce the likelihood of upper limb injury resulting from long-term manual wheelchair use. The custom-designed and custom-built frame also decreases the weight and improves durability of the frame, further maximizing functionality for performance of routine ADLs and IADLs in all typical environments.

Tilite TR – Made to Measure K0009 MWC Case Example

Erin Bischofberger, PT, DPT, ATP
Allison Fracchia PT, ATP/SMS
Methodist Rehabilitation Center
Jackson, MS

"Tom" is a 39-year-old male who had a spinal cord injury in 1993 resulting in C-7 quadriplegia. He is 6'4" and weighs 190 pounds. He is an extremely active individual who propels his manual wheelchair several miles each day over various types of terrain to get to his job in town. He has recently been hired for a part time job that requires cleaning and repairing the inside and outside of vehicles, but is having difficulty reaching into the vehicles. With the design and configuration of his current wheelchair, he cannot get close enough to the vehicle and his stability in the wheelchair is compromised when reaching forward. In addition, the wheelchair is in a state of disrepair. Tom lives in a completely accessible mobile home with a ramp for entrance and egress. He is independent with all transfers to and from the wheelchair including bed, car, floor and same level surfaces. He is also independent with self-care, dressing, bathing, eating, tabletop activities, and all other routine ADLS within the home.

Tom currently uses a Tilite Aero Z K0005 manual wheelchair that he obtained in March of 2010. It is of proper width and depth. The chair is set up with a 2" difference between the front and rear seat to floor height to create a minimal seat squeeze. The angle of the front frame is 80° relative to the floor <u>and</u> 80° relative to the seat rail/side frame of the wheelchair. Tom is able to reach forward 4" prior to a loss of balance and trunk stability. He complains that his feet slide forward off of the footrest when navigating the chair on uneven surfaces, but he does not contribute this to spasticity as this is managed by oral baclofen.

Despite multiple repairs over the last year, his wheelchair has the following problems:

1. Right adjustable caster housing assembly is bent and damaged beyond repair
2. Casters need replacement despite replacement three months ago
3. Sling upholstery has significant wear and tear which is placing him in a more sacral sitting position
4. Wheel locks and wheel lock assemblies are missing off the left side
5. Side guards are cracked with plastic sharp edges exposed
6. Left push handles/adjustable back canes are slightly bent causing him to sit with a right trunk rotation
7. Rear tires have no tread and need replacement
8. Many of the bolts for the adjustable components of the wheelchair have wallowed out resulting in a significant amount of "play". This includes the bracket that attaches the backrest to the seat rails.
9. Frame is not level when placed on a level surface due to bent caster housing and bent frame. This causes poor tracking and veering towards the right

The following information was obtained during the evaluation:

Anatomical Measurement	**Left**	**Right**
Thigh length	24"	23"
Lower leg length	21"	20"
Shoulder height	25.5"	24
Hip width	16.5"	

Passive range of motion was within normal limits for both upper and lower extremities. There was no increase of tone noted during testing. Strength in both upper extremities was good (4/5) with exception of his hands, which had no functional strength. Muscle strength in the trunk and both lower extremities was absent.

When seated in his current wheelchair, Tom presented with a posterior pelvic tilt, increased thoracic kyphosis with shoulder protraction, bilateral hip internal rotation with adduction, and a forward head. He also has a right pelvic obliquity with right trunk rotation. The mat evaluation demonstrated that the trunk rotation, pelvic obliquity, thoracic kyphosis, shoulder protraction and hip position were flexible and could be corrected. His posterior pelvic tilt could be corrected slightly. Tom had fair sitting balance, good head control, and fair trunk control.

During the evaluation, Tom demonstrated independence in higher mobility skills such as popping wheelies, navigating down a 2” curb, and propelling up and down ramps. He is able to propel his chair on grass, gravel, smooth and unlevel surfaces. When descending hills he decelerates by running the palmer surface of his hands bilaterally on the spokes of the wheelchair.

Tom is non-ambulatory and is unable to functionally propel a standard weight (K0001), lightweight (K0003) or high strength lightweight (K0004) manual wheelchair in which the axle is located posteriorly to his shoulder joints. During trials with a K0004, he displayed difficulty popping wheelies and could not manage a ramp with a 10% grade. It took him 13 seconds to propel 15 feet. Use of this type of chair would limit his ability to manage his chair over thresholds, enter and exit his home via the ramp, and navigate on surfaces other than smooth, level terrain. He is however, able to functionally self-propel a custom ultra-lightweight (K0005) wheelchair. He could propel 15 ft. in 8 seconds, was able to propel up and down ramps and over both smooth and uneven surfaces. The ability to position the rear axle slightly anterior to his shoulder joint significantly impacted his functional mobility. However, he was not able to achieve the combination of seat squeeze and front frame angle necessary for the degree of forward reaching and front access that he needed.

Other wheelchairs that were considered but eliminated during the evaluation included:

1) Power wheelchair – Tom has no way to transport a power chair. In addition, during a trial with a power wheelchair in the past, he experienced several occasions in which the battery “died” as he was navigating the chair within the community. Tom feels that a power wheelchair does not work for his level of activity during the day and he feels more confident with use of a manual chair.
2) Another K0005 rigid frame wheelchair - this was ruled out due to the fact that he currently has a very high end, high quality K0005 wheelchair, which is in a state of disrepair after only 2 years, despite the expected typical life of 5 years. It would not make financial sense to replace his current K0005 wheelchair with another K0005 chair.

   Another K0005 wheelchair was also ruled out due to limitations in attaining the required degree of seat squeeze combined with the required angle of the front frame. The evaluation demonstrated that Tom requires a significant amount of frame squeeze (4")for optimal trunk stability and maximum forward reach, but he also needs to have his feet “tucked” back as far as possible under the seat (10° degrees behind his knees) to enable him to get as close as possible to objects for a functional reach. Adjusting the K0005 to achieve the 4" of seat squeeze would automatically increase the front frame angle. This would increase the overall “footprint” and maneuverability of the chair. The K0005 wheelchair is not able to achieve the combination of seat angle and frame angle that was required for posture, stability and accessibility.

3) Heavy duty option on a K0005 chair - although a heavy-duty option provides increased frame strength, it also adds increased weight due to the extra material and heavier hardware. Due to his high activity level and compromised upper extremity function and the fact that he is a long term manual wheelchair user, it is imperative that he receive the most lightweight frame possible. In addition, a heavy duty option on a 16” wide frame would necessitate a “custom” modification that would be very expensive.

Tom was also able to triall a Tilite TR manual wheelchair during the evaluation. This demo wheelchair was equipped with plastic coated rims, a 4" difference between the front and rear seat to floor height (4" seat squeeze) and adjustable tension back upholstery. The frame was custom configured to allow this degree of squeeze while still maintaining a front frame angle of 80° degrees relative to the floor. Tom demonstrated significantly improved stability and balance and was able to reach 3” further forward compared to when seated in his current wheelchair (for a total of 7"). Tom found the Tilite TR much easier to propel due to the decrease in weight.

In the Tilite TR, Tom was able to navigate on a variety of different surfaces, go up and down a ramp, maneuver down a 2” curb drop and turn sharply in a confined, tight elevator space. He was able to perform all of these activities without having to reposition his feet on the footplates. With the tight front bend of the Tilite TR, he was able to pull up closer to a surface. Although this “tucked” position required increase knee flexion, he was able to maintain his position while performing numerous functional activities. In addition it actually improved navigation in tight confined spaces due to the decreased overall “footprint” of the frame.

Tom has demonstrated that a K0005 wheelchair no longer meets his needs. The connections that allow adjustment of the backposts and the caster housing and the frame itself will not hold up to his high activity level. In addition, no K0005 can provide the combination of seat angle (squeeze) and front frame angle that are required for stability and function. Overall, the K0009 Tilite TR non-adjustable frame was the only appropriate choice. The front and rear seat to floor heights are custom configured and manufactured at the factory resulting in a configuration that meets his postural and functional needs. The lack of adjustment in the seat angle, back posts and rear wheel position eliminates the nuts, washers, and bolts and should provide a more durable and lighter frame. The Tilite TR meets Tom’s needs for posture, function and activity level.

Quickie Q7 Active Rigid - Made to Measure K0009 MWC Case Example

Jill Monger PT, MS, ATP
Medical University of South Carolina
Wheelchair Seating and Mobility Clinic

"Tracey" is a 48 year old female who fell from an extreme height on 12/16/1996 with resultant T12 ASIA A spinal cord injury. She also experienced a fall from her wheelchair in 2000 resulting in cervical injuries including a bulging disc at C5 and ongoing degenerative joint disease at C4. In early 2001, Tracey experienced a right shoulder labrum tear and underwent arthroscopic surgery followed by a full open repair procedure in November 2001. She reports continued pain with over activity of this shoulder. She also now has left shoulder pain due to overcompensation for her right shoulder. She has been diagnosed with bilateral carpal tunnel syndrome, progressive arthritis in both hands and has had surgical releases of bilateral trigger fingers in 2002.

Tracey reports significant mid-thoracic and low back pain and buttock pain when seated in the wheelchair, all of which are attributed to a combination of musculoskeletal and neurogenic pain. She has a long history of severe spasticity and pain, requiring a Baclofen pump placement in May of 2000. She is currently using the pump for neurontin to relieve nerve pain, and narcotics to relieve other pain, in addition to the Baclofen for spasticity.

Tracey owns a fully accessible home where she resides with her partner. She drives a pickup truck and lifts her wheelchair in and out of the cab of the vehicle independently. She transfers herself independently in and out of the truck with a hydraulic lift system that lowers for transfers. She estimates that she transfers in and out of her truck 8-12 times on a typical day. She is highly active in the community, with involvement in disability advocacy, assisting with physical education and sports for disabled students, local wheelchair sports teams and performing her own household and personal errands. She also visits other individuals with disabilities in their homes and in rehab settings in her work as a peer counselor.

Tracey's PROM is as follows: full in both upper extremities, except for limitations in her distal finger joints due to deformity; full in the trunk; functional in the neck; hip flexion range is 10 - 120° bilaterally; knee flexion range is 10 - 140° bilaterally (lacking about 10 degrees of extension with hip extension). Hip and knee ROM have improved since getting a stationary stander earlier this year; ankle dorsiflexion with knees extended is 5° degrees bilaterally. Strength in both upper extremities is 4/5 with limitations due to pain. Tracey has no active movement in her trunk or lower extremity muscles. Tracey sits in a posterior pelvic tilt and right low obliquity, both of which are flexible. She has good sitting balance short term but fatigues easily and falls into a posterior pelvic tilt when sitting on a flat surface in vertical orientation. This leads to back pain, buttock pain and shoulder pain.

Tracey relied on custom made to measure MWCs (K0009) for many years. This included a Quickie Ti titanium MWC, which she used until 2007, when she received her current adjustable Quickie GT (K0005) MWC. The GT was selected as a cost saving option by Workers Compensation. Although she has owned the GT for 5 years, she reports that she has returned to using her old Quickie Ti, even though it is in disrepair, due to issues with the GT. Tracey finds the GT more difficult to maneuver in the community and not as responsive as her Quickie Ti. In addition she reports that the GT is much more difficult to lift in and out of her vehicle. She finds that she experiences a significantly higher pain rating by the end of the day when using the GT.

During the examination and trial we found that by adding an 8"Jay 3 backrest Tracey was able to maintain her pelvis in a more neutral position without active holding. We also found that a more supportive contoured Jay 3 cushion with pelvic positioning helped to maintain her pelvis in a neutral position. The improved posture along with the pressure redistribution materials in the cushion helped to decrease the pain in her buttocks and back. With a more neutral upright position her shoulder girdle was aligned more closely with the rear wheel, which should improve her propulsion stroke.

Tracey tried the Jay 3 cushion and back support described above on both her current GT and her old Quickie Ti. Observation of her propulsion stroke in the GT revealed increased upper trunk movements during the push phase. These trunk movements changed the alignment of her shoulder with the rear wheels, which limited her shoulder extension range and resulted in a shorter stroke and need for increased force per stroke. In contrast, in her old Quickie Ti her shoulders remained over her hips (and the rear wheels) during the push phase, allowing improved shoulder extension and a full stroke to minimize the force required per stroke. When Tracey was observed lifting both the GT and the Quickie Ti in and out of the truck, it was obvious that she experienced less strain when transporting the Quickie Ti.

Tracey's goals are to relieve her back pain and buttock pain when in the wheelchair, to minimize the stress on her upper extremities and protect her shoulder, elbow, wrist and hand joints from further damage, and to continue to be independent for all her mobility needs in all her varied activities throughout the day. This necessitates transporting her wheelchair in and out of her truck multiple times per day.

Her current GT K0005 wheelchair is an adjustable high strength ultralight weight aluminum frame that is adjusted and configured for her size. It does not, however have the same specific combination of configurations (seat squeeze, front frame angle, seat to floor height, rear wheel position and frame length) as her Quickie Ti and other previous custom made to measure wheelchairs. The configurations provided by these wheelchairs provided the most intimate fit and ergonomics for Tracey. In addition, the frame of the GT is approximately 19 lbs, while the Quickie Ti is only 13 lbs, a significant difference for an active long-term wheelchair propeller with upper extremity pain and injury. The weight distribution of the GT also changes the balance of the wheelchair during propulsion, making it more difficult for her to propel. This, combined with the frame design and shape make it more difficult for her to lift the wheelchair in and out of the truck. Another K0005 would have the same issues. The only appropriate wheelchair for Tracey's needs is a custom made to measure wheelchair with the specific combination of configurations that she has had on her previous wheelchairs.

The following equipment is recommended for Tracey.

Quickie Q7 Active Rigid K0009 MWC to provide the custom configurations required for function and preservation of her upper extremities. A K0005 does not have the weight or the combination of configurations and features that provide her with the most intimate fit and ergonomics. This is critical considering her pain, surgeries, injuries, arthritis and spasticity.

25" Spinergy wheels with high-pressure clincher tires to provide a rim and tire combination that is ultralight and very high strength with excellent performance. This will decrease rolling resistance when propelling and will further reduce the stress of transporting the chair. Tracey has used Spinergy wheels successfully for 13 years.

Jay 3 cushion with air insert to provide pressure redistribution and added pelvic stability for improved propulsion stroke. The materials will also help to reduce buttock and back pain.

Jay 3 backrest to provide stability and support for her spine without significant added weight

Frog leg casters to provide the necessary suspension to reduce back and buttock pain and to prevent triggering of her spasticity when traversing over uneven terrain and over thresholds. Tracey has used suspension casters on her previous wheelchairs with excellent results.

Natural Fit handrims (small sized) to continue to prevent/minimize her carpal tunnel symptoms, shoulder strain and pain. The Natural-Fit Handrim provides an ergonomic design and separate surfaces for propulsion and braking that reduce stress on the hands, wrists, arms and shoulders when propelling a manual wheelchair. Tracey has used these handrims successfully for over 5 years.

Angle adjustable footplate to accommodate ankle joint tightness and clonus.

Leg straps to prevent knee flexion when leaning forward (this occurs due to spasticity and feet come off the footplates causing her to fall forward.

Custom Made To Measure Manual Wheelchairs – Evidence Summary

Custom made-to-measure manual wheelchairs play a critical role in meeting the needs of and optimizing function for the users described in the "Clinical Indications and User Characteristics." This technology has several unique characteristics that allow specific and precise configuration to meet the needs of individuals who use them. There is a large and growing body of research literature supporting the many benefits of individually prescribed and optimally configured manual wheelchairs, which include: improved posture, increased user satisfaction and self reported quality of life, gains in activity and participation, and reduced biomechanical stresses critical in the prevention of overuse injuries in manual wheelchair users. Research literature in each of these areas is summarized below and the articles cited are included in their entirety following this summary.

Several researchers have indicated benefits from proper configuration of seat inclination (seat squeeze), back support inclination (seat to back angle), and back height (Alm, Gutierrez, Hultling, & Saraste, 2003; Bolin, Bodin, & Kreuter, 2000; Hastings, Fanucchi, & Burns, 2003; Maurer, 2004). One possible concern with increased seat inclination might be an adverse effect on seat interface pressure; however Maurer (2004) showed no such effect in interface pressure characteristics based on these changes. In a study conducted by Hastings et al. (2003), optimal configuration of seat inclination and back height improved posture and functional reach of individuals with spinal cord injuries. Likewise, Bolin et al. (2000) assessed the impact of individual configurations of manual wheelchairs for individuals with tetraplegia or paraplegia and found improved posture, balance and function in subjects following a customized wheelchair seating intervention. Alm, et al. (2003) focused on clinical evaluation methods, but determined that standard wheelchair configurations were lacking in providing optimal postural support for individuals following spinal cord injury. All of these studies found significant benefit to careful application of an individualized configuration of key angles, including seat inclination and back support angle, as well as provision of properly fitted width and height dimensions of the seat and back supports of manual wheelchairs.

Researchers have also examined the impact of individually-configured wheelchairs based on the needs of the user. These studies have looked at the needs of individual wheelchair users (Batavia, Batavia, & Friedman, 2001) and of various groups of users (Trefler, Fitzgerald, Hobson, Bursick, & Joseph, 2004) of wheelchair users. Batavia et al. (2001) focused on the need for careful consideration of all relevant factors when prescribing a wheelchair for an individual user and notes the importance of careful measurement and configuration of a wheelchair to meet the individual needs of the user. Although this work was not focused on any one type of wheelchair, he cautions that any wheelchair must be configured to meet the needs of the user for whom it has been prescribed. Trefler et al. (2004) examined the effects of providing an "individually prescribed seating and mobility system" for older adults living in a long term care facility. The researchers who performed this study found significant improvements in mobility, functional reach tasks, the feeling of well being and satisfaction of the wheelchair users as a result of provision of these systems that were designed and configured to meet the needs of these users.

Other researchers who investigated the impact of manual wheelchairs on maneuverability, found that rigid frame ultralight weight wheelchairs were the most maneuverable for users (Koontz, Brindle, Kankipati, Feathers, & Cooper, 2010). Several other studies have highlighted the importance of wheelchair technologies on the lives of individuals who use them (Anneken, Hanssen-Doose, Hirschfeld, Scheuer, & Thietje, 2010; Carlson & Myklebust, 2002; Chaves et al., 2004; Eriks-Hoogland, de Groot, Post, & van der Woude, 2011). Although these studies employ different methodologies with different populations of wheelchair users, they all highlight the importance and the impact of having a properly configured manual wheelchair on the lives of the individuals who use them. Favorable benefits include increased levels of social participation and activity and reduction of health complications common among wheelchair users.

One of the most well researched topics related to the impact of optimal configuration of a manual wheelchair system is the prevention of overuse injuries to the upper extremities. These overuse injuries include carpal tunnel syndrome and median nerve mononeuropathy (Gellman et al., 1988; Yang et al., 2009), and various shoulder injuries (Boninger et al., 2003; Boninger et al., 2005; Requejo et al., 2008). All of these researchers indicate the high prevalence of these injuries, and highlight the need to have optimally configured manual wheelchair systems to reduce biomechanical forces and minimize the use of injurious kinematics. One of the primary strategies to reduce propulsion forces and optimize propulsion patterns revolves around proper configuration and fit of the wheelchair. These are major goals achieved by custom made-to-measure manual wheelchairs for any manual wheelchair user who requires a specific configuration that is not achievable on an adjustable manual ultralight weight wheelchair.

In addition to this significant body of evidence devoted specifically to the prevention of upper extremity overuse injuries among manual wheelchair users, there is an equally impressive literature base that related to such topics as: kinematic concerns during transfers into and out of a manual wheelchair (Finley, McQuade, & Rodgers, 2005), kinetics, or forces, during start up of propulsion on different surfaces (Koontz et al., 2005), energy costs of propelling standard vs. ultralight weight manual wheelchairs on level surfaces (Beekman, Miller-Porter, & Schoneberger, 1999), and EMG changes resulting from different wheelchair configurations, particularly related to the seat height and the fore/aft axle position (Louis & Gorce, 2010). Researchers in each of these studies employed different methodologies and different outcome measures, but all reached similar conclusions that optimal configuration of wheelchair dimensions (e.g. seat height and inclination, back support angle and height) as well as using the lightest weight system possible have positive impacts on the function and safety of manual wheelchair users.

In addition to these studies, several studies have focused on shoulder biomechanics (kinematics and kinetics) of wheelchair propulsion and how these biomechanics are affected by various wheelchair configurations. Collinger (2008) compared shoulder kinetics and kinematics across different wheelchair propulsion speeds and found significant differences in forces related to speed and user weight. Hurd et al. (2008) examined the propulsion characteristics across different ground surfaces and found significant differences related to rolling resistance of the wheelchairs. Other researchers found differences in biomechanics based on seat system tilt and back recline angle (Aissaoui, Arabi, Lacoste, Zalzal, &

Dansereau, 2002) and in wheelchair users who already have upper limb impairments (Finley, Rasch, Keyser, & Rodgers, 2004). Although there is significant variety in parameters tested across these studies, the results highlight the many user and environmental characteristics that have significant impact on the biomechanics of wheelchair propulsion.

Probably the most crucial characteristics of manual wheelchair configuration, and certainly the most heavily researched, are the effects of fore/aft rear axle position and the effects of different seat heights. Several researchers have conducted studies in which both of these characteristics were varied, whereas others only varied one of these critical characteristics. All demonstrated differences in outcomes related to propulsion kinetics or physical strain associated with the location of the rear axle of the wheelchair in relationship to the user. This is one of the key characteristics in a custom made to measure manual wheelchair and one of the key benefits of this type of wheelchair is the ability to configure this optimally for an individual user. Several researchers have found significant differences in propulsion strain and forces based on varying seat height (Boninger, Baldwin, Cooper, Koontz, & Chan, 2000; van der Woude et al., 2009). Others have found significant advantages to a forward axle position, or rearward seat position (Gutierrez, Mulroy, Newsam, Gronley, & Perry, 2005; Kotajarvi et al., 2004; Mulroy et al., 2005). Additional researchers have found optimal speed and acceleration characteristics with a combination of seat height and forward axle position (Freixes et al., 2010). Additionally, Cowan (2009) indicated positive benefits of an 8 cm change in axle position on propulsion biomechanics. Although there were threats to external validity noted in a follow up commentary (Sprigle, 2009) to this study, the study was noted to have adequate internal validity, though it may be lacking in sufficient sensitivity to be generalized to smaller changes in axle location. All of these studies highlighted the propulsion benefits of configuring the rear axle in an optimal location to minimize propulsion forces and therefore minimize stress on the shoulder joints.

Although there is still a need to continue research into the benefits of custom made-to-measure manual wheelchairs, this body of evidence is indicative of the many benefits of this type of technology. There is certainly a subset of manual wheelchair users whose wheelchair configuration needs cannot be met by an adjustable manual ultralight weight wheelchair and who therefore will benefit greatly from the customized configurations and unique fit of the custom made to measure wheelchair. Further study will continue to confirm these needs and reinforce the benefits of these wheelchairs.

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Product Characteristics - Bariatric MWC with Special Features

Manufacturer	Chair	Seat depth adj.	Seat/Frame depth adj.	Seat/Frame angle adj.	Seat/Frame angle capability	Seat to back angle adj.	Tilt range	Back height adj	Floor to seat height adj.	Rear wheel position adj.	Rear camber & Lateral Rear Wheel width capability	Width adj.	User Weight Limit	Std seat to floor height(s)	Std seat depth(s)	Std frame depth(s)	Std seat width(s)	Std back height(s)	Frame Warranty	Optional armrests	Optional footrests	Optional footplates	Excepts multiple rear wheels /tires	Excepts multiple castor wheels /tires
SUNRISE MEDICAL (US) L	QUICKIE M6			Yes	7.2 °			3"	No	2"	No camber adjustment, 1"	No	650Lbs	17",18.5",20"	18"-22"	2	22"-30"	16.75-20.125"	Lifetime	Ht Adj Dual Posts, Full or Desk Armpads	60 °Swing Away Ext Mounted, ELR, 70 & 80 Front Mount Lift Off	Composite,Adult Angle Adj, & Aluminum	24" Spoke Wheels	5"Soft Roll, 8"-Pneu, 8"x2" Pneu w/insert
PDG PRODUCT DESIGN GROUP INC	Eclipse 600	16"-20"		No		Yes			Yes	Yes		20"-36"	600 -1000 lbs	14" - 18"	16"-20"		20"-36"	25" or 30"	Lifetime	Yes	Yes	Yes	24" Only	5" Only

CLINICAL INDICATIONS AND USER CHARACTERISTICS

BARIATRIC MANUAL WHEELCHAIRS WITH SPECIAL FEATURES

An individual who requires a bariatric manual wheelchair with special features uses the wheelchair for his/her primary means of mobility and is either dependent in mobility or is able to propel independently in environments of typical use to complete routine ADLs and IADLs. He/she requires one or more of the following features that are not available on a standard heavy duty or extra heavy duty wheelchair but may be available on a bariatric manual wheelchair with special features:

- Horizontal rear wheel adjustment for forward wheel positioning
- Adjustable seat to back angle (to provide a limited fixed recline)
- A range of available seat to floor heights
- Minimal fixed tilt in the frame
- Adjustable back height
- Significantly lighter frame weight than a comparably sized standard heavy duty or extra heavy duty wheelchair

The individual may require these features due to one or more of the following:

- Is at risk for upper extremity repetitive strain injuries from long term wheelchair propulsion due to upper extremity muscle weakness or paralysis, increased or decreased muscle tone, compromised joint integrity and/or decreased range of motion or contractures in the upper extremity(s), trunk or neck, all of which are compounded by increased body weight.
- Is unable to safely and efficiently propel the weight of a standard heavy duty or extra heavy duty wheelchair to complete routine ADLS and IADLs in environments of typical use due to upper extremity weakness, paralysis or pain, decreased endurance, increased or decreased muscle tone, decreased range of motion or contractures in the upper extremity(s), trunk or neck and/or decreased upper extremity motor control, all of which are compounded by increased body weight.
- Requires a specific non-standard seat width or depth and/or back width or height to maintain optimal posture for maximum function (i.e. upper extremity propulsion) and/or to maintain skin integrity.
- Requires a specific (lower) seat to floor height to allow efficient propulsion with one or both lower extremities while maintaining optimal upright and midline posture
- Requires a minimal fixed tilt in the frame for gravity assisted positioning to maintain optimal posture for maximal function due to weakness or paralysis of neck, trunk or pelvic muscles, pain, poor endurance, increased or decreased muscle tone, impaired cognition, and/or increased fatigue.
- Requires a seat to back angle greater than 90 degrees to maintain optimal posture for maximal function or to accommodate or support a fixed postural deformity due to weakness or paralysis of neck, trunk or pelvic muscles, contractures or orthopedic deformity(s), pain, atypical body morphology due to obesity, poor endurance, increased or decreased muscle tone, and/or increased fatigue
- Requires forward repositioning of the rear wheels to alleviate the increased loading of the front casters and the decreased access to the rear wheels that results from atypical body morphology due to obesity (e.g., significant pannus size or weight)

M6- Heavy Duty Adjustable Axle MWC Case Example

Allison Fracchia PT, ATP/SMS
Methodist Rehabilitation Center
Seating and Wheeled Mobility Clinic
Jackson, MS

"Ann" is a 36 year old female with a diagnosis of left above knee amputation as a result of complications from a dislocated knee and lacerated popliteal artery. The amputation occurred approximately 1 month ago. She is 5'4" and weighs 320 pounds. Past medical history is significant for hypertension, morbid obesity, and non-insulin dependent diabetes mellitus. Ann lives in an apartment with her mother and 10 year old son. The apartment is handicap accessible and located on the ground level. There is no need for a ramp and all doors are 36" throughout. Prior to these medical complications, she drove a 1993 Chevy Caprice car.

Ann is able to bathe, feed and groom herself independently from a seated position. She requires minimal assistance for dressing since she is unable to don/doff her right sock and shoe and has difficulty managing her pants. Ann can perform table top activities independently from a seated position. She does require minimal assistance to transfer to and from the bed using a sliding board. She requires maximal assistance for car and floor transfers.

Ann had complications with healing of the left leg wound following the amputation and is not a candidate for a prosthesis. She is unable to support her weight using her upper extremities with crutches or a walker. Goals are geared towards wheeled mobility as her primary means of mobility in the home setting.

During the evaluation, Ann demonstrated an increased thoracic kyphosis which was flexible. Passive range of motion was within normal limits throughout except for hi p flexion which was limited to 80° due to interference with excessive abdominal tissue. Sitting balance was good for static and dynamic activities. She exhibited good head and trunk control. Measurements taken in short sitting on the edge of the mat were as follows: hip width is 25"; thigh length is 22.5" on the left and 23.5" on the right (due to significant posterior tissue); right lower leg length is 17"; seat to shoulder height is 19"; seat to axilla is 11". Strength was normal in both upper extremities and the right lower extremity. There was no increase in tone noted during testing.

Ann was provided with a standard heavy duty loaner manual wheelchair to use while she was in the hospital. This wheelchair had a seat width of 24" and a seat depth of 16". With this chair, she is only able to propel on level, smooth surfaces for short distances and required 10 seconds to propel a distance of 5'. She cannot reach both handrims at the same time to propel the chair because the rear wheels are positioned so far from the side frames. In addition, the wheels are located posterior to her shoulder joints which results in extreme shoulder retraction of her shoulder girdle and shoulder extension during attempts at propulsion. This places strain on the anterior capsule of the glenohumeral joint. Ann also experiences pressure and pain on her inner arm from rubbing on the armrest during attempts at propulsion. The short seat depth of the standard chair does not provide sufficient support under her thighs, causing hip abduction and external rotation. Ann was unable to sit in the standard (fixed) 90° seat to back angle of this chair due to her excessive abdominal tissue, which prevented 90° of hip flexion. This caused her to slide forward into a posterior pelvic tilt, which further decreased her access to the handrims.

A standard, lightweight, high strength lightweight and ulralightweight manual wheelchairs are inappropriate for Ann due to their inadequate weight capacity. A heavy duty scooter would not fit in her home due to its wide turning radius. It would also not allow her to pull up close enough to counter tops and table tops, limiting her ability to perform her ADL's.

Ann was able to trial a Quickie M6 (K0009) manual wheelchair during the evaluation. The rear wheel of the M6 can be adjusted forward on the frame to more closely align with her shoulder joint for improved shoulder position and increased ability to propel. In addition, the rear wheels could be brought in closer to the side frame for increased handrim access. This allowed her to reach both wheels simultaneously for propulsion. Along with removal of the handrims, it also decreased the overall width of the chair, allowing increased accessibility within her home. The armrest pads could be reverse mounted to decrease the amount of friction on her arms during propulsion.

With the adjustable backcanes of the M6, the seat to back angle could be opened to 110°. This conformed to Ann's hip angle and anatomical shape and allowed her to maintain her pelvic position in the chair. It also improved shoulder alignment with the rear wheel. This gave her increased access to the rear tires while promoting upright posture and decreasing the thoracic kyphosis that was noted when she attempted to propel the standard heavy duty wheelchair. The M6 was also able to provide a seat depth of 22", which resulted in better pressure redistribution and thigh support to decrease Ann's hip abduction and external rotation while seated in the chair. This also helped to decrease the degree of posterior pelvic tilt and resulting pressure on the sacrum.

The M6 is significantly lighter than the standard heavy duty wheelchair. Ann will be a long term wheelchair propeller and must propel the weight of the wheelchair plus her increased body weight. It is critical to provide the lightest wheelchair possible to reduce the risk of repetitive strain injuries of the upper extremities.

With the adjustments and configurations provided by the M6, Ann demonstrated the ability to maneuver the wheelchair on carpeted and uncarpeted surfaces, in and out of a doorway, up and down a congested hallway, and making a u-turn independently. She was able to propel farther and quicker in the M6 compared to the standard heavy duty wheelchair. She found it much easier to propel and she was pleased with the outcome. This M6 not only improved her increased functional mobility but also improved her seated posture both in static and dynamic activities. This will decrease her risk of development of skin breakdown, postural abnormalities (which can lead to respiratory and pain complications), and orthopedic upper extremity overuse injuries.

Bariatric Manual Wheelchairs with Special Features- Evidence Summary

Unfortunately, there is a large and growing population of individuals with disabilities who are severely obese in the United States and many other countries around the world. The risk of obesity is also higher among persons with other disabilities, such as spinal cord injury (Fitzgerald & Kelleher, 2007). In spite of this, there exists a dearth of research specifically related to manual wheelchair technologies, or mobility assistive devices in general, for the bariatric population.

What is better understood is that the benefits of features such as axle position adjustability and different configurations of seat tilt, back recline, back height and foot support positions and locations that apply to other populations of wheelchair users also apply to bariatric technology users, at least to some extent. Specific configuration of seat and back angles and seat and back heights can still facilitate upright posture and function (Hastings, Fanucchi, & Burns, 2003). Location of the axle as far forward as possible and positioning the height of the seat to optimize wheel contact will still facilitate optimal propulsion biomechanics, wheel access, and offloading of the front casters (Boninger, Baldwin, Cooper, Koontz, & Chan, 2000; Freixes et al., 2010; Kotajarvi et al., 2004; Mulroy et al., 2005; van der Woude et al., 2009). We know that seat and back angle configuration will also facilitate wheelchair propulsion, just as it does in the elderly population (Aissaoui, Arabi, Lacoste, Zalzal, & Dansereau, 2002). It is also very likely that the concepts related to and benefits of shoulder joint preservation also applies to this population, although certainly some of the challenges may differ (Requejo et al., 2008).

The applicability of these concepts to this population is supported by Fitzgerald and Kelleher (2007), in the one major research publication related to persons with both obesity and spinal cord injury. Bariatric manual wheelchair configurations are as critical or perhaps more critical to individuals with obesity as they are for those who are not obese and require optimal configuration for manual wheelchair propulsion. The challenging anthropometrics of individuals with obesity require customization in configurations of the seat, the back support, arm and leg supports and rear wheel or propulsion wheel position. Without the ability to customize or optimize these features of a manual wheelchair, it might be impossible for an individual to sit safely in the wheelchair and to gain any level of independence in propelling the wheelchair either independently or with assistance.

Bariatric Manual Wheelchairs With Special Features References:

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Product Characterics - Standing MWC

Manufacturer	Chair	Seat depth adj.	Seat/Frame depth adj.	Seat/Frame angle adj.	Seat/Frame angle capability	Seat to back angle adj.	Tilt range	Back height adj	Floor to seat height adj.	Rear wheel position adj.	Rear camber & width capability	Width adj.	User Weight Limit	Std seat to floor height(s)	Std seat depth(s)	Std frame depth(s)	Std seat width(s)	Std back height(s)	Frame Warranty	Optional armrests	Optional footrests	Optional footplates	Excepts multiple rear wheels /tires	Excepts multiple castor wheels /tires
Permobil	Permobil Lifestand Helium LSA	16" to 21" adj	16" to 21" adj		Appx 3 degree only	Minus 3 degrees to Plus 12 degrees		Optional 15" to 19" adj.	Minimal (1" higher only)	4.5" adj. Fore/Aft only	0 or 3 degrees optional (fixed)		220 lbs.	20"	16" to 21" adj	16" to 21" adj	15", 15.5", 16", 16.5", 17.5", 18"	13" fixed - Std. 15" to 19" adj. - Optional	5 years	Swingaway Padded	Fixed	Footplate/one piece fixed only *Height and Angle adj.*	24" or 26" wheels Multiple tube/tires	4" soft roll 4" Polyure. 6" Polyure.
Permobil	Permobil Lifestand Helium LS	15" to 21.5" adj	15" to 21.5" adj		Appx 3 degree only	Minus 3 degrees to Plus 12 degrees		N/A	Minimal (1" higher only)	4.5" adj. Fore/Aft only	0 or 3 degrees optional (fixed)		265 lbs.	20"	15" to 21.5" adj	15" to 21.5" adj	14", 16", 17.5", 19"	12.5", 16", 20" non-adjustable	5 years	Flip-up Padded Depth adj. Height adj. Rotate lateral	Fixed or Swing-away	Footplate/dual flip-up Footplate/one piece flip-up Footplate/one piece fixed *All are Height adj. and Angle adj.*	24" or 26" wheels Multiple tube/tires	6" Polyurethane only
Permobil	Permobil Lifestand Helium LSE	15" to 21.5" adj	15" to 21.5" adj		Appx 3 degree only	Minus 3 degrees to Plus 12 degrees		N/A	Minimal (1" higher only)	4.5" adj. Fore/Aft only	0 or 3 degrees optional (fixed)		265 lbs.	20"	15" to 21.5" adj	15" to 21.5" adj	14", 16", 17.5", 19"	12.5", 16", 20" non-adjustable	5 years	Flip-up Padded Depth adj. Height adj. Rotate lateral	Fixed or Swing-away	Footplate/dual flip-up Footplate/one piece flip-up Footplate/one piece fixed *All are Height adj. and Angle adj.*	24" or 26" wheels Multiple tube/tires	6" Polyurethane only
The Standing Company	LIFESTAND																							
The Standing Company	SUPERSTAND STANDING WHEELCHAIR																							

CLINICAL INDICATIONS AND USER CHARACTERISTICS

STANDING MANUAL WHEELCHAIRS

An individual who requires a standing manual wheelchair uses the wheelchair for his/her primary means of mobility and is able to propel independently. This individual is unable to stand without assistance. He/she has the need for the features of an ultralightweight manual wheelchair plus an integrated standing system in order to stand independently and intermittently throughout the day to participate in routine ADLs and IADLs. This includes the need to access variable heights in different locations in routinely encountered environments. These activities may include, but are not limited to stove top cooking, accessing cabinets, refrigerator or microwave, washing dishes, loading and unloading the washer and dryer, accessing clothes or other objects in closets, accessing sinks and bathroom mirrors, toileting, grocery shopping, and/or child care (accessing a crib). A dedicated stationary standing frame would not provide the mobility required to access all necessary locations for completion of daily activities.

These individuals require the medical and/or functional benefits of standing. For some, these needs may be met with the periodic positioning provided by a dedicated stationary standing frame. For others, however, these needs can only be met with the frequent transitions from sit to stand and the frequent, prolonged and cumulative standing that can only be achieved by a combination of a wheelchair and a standing device. These needs include one or more of the following:

- Risk of skin breakdown from prolonged sitting and/or ineffective weight shifts requiring the maximum pressure redistribution achieved in the standing posture. The frequency and duration of the required weight shifts cannot be reasonably accomplished in a tilt in space and/or recliner manual wheelchair due to the disruption of routine ADLs and IADLs during tilt and/or recline.
- Bowel and/or bladder impairment resulting in urinary tract infections, bladder infections, constipation and/or kidney stones due to compromised bladder or bowel elimination exacerbated by prolonged sitting.
- Increased tone in the lower extremities, pelvic and trunk muscles that is diminished in the standing posture with prolonged weight bearing though the lower extremities
- Decreased bone mineral density in the lower extremities due to lack of weight bearing from prolonged sitting
- Presence of or risk of joint contractures due to prolonged positioning in a seated posture
- Joint pain caused by static positioning and/or intervertebral loading in the seated posture

Helium - Standing MWC Case Example

David Kreutz, PT, ATP
Physical Therapist, Seating Clinic Coordinator
Shepherd Center
Atlanta, GA

Seating and Mobility Evaluation Report:
Name: John
Height 67”
Weight 115
Referring MD: S. Jones

“John” is a 25 y/o male who was involved in a motor vehicle accident in 2009 resulting in a primary diagnosis of T-3/4 complete paraplegia with secondary diagnoses of joint motion limitation (719.5), muscle atrophy (728.2) and spasticity (728.85). John has no presence or history of pressure ulcers however; he is at high risk due to significant muscle atrophy of the buttocks and leg muscles. He has no other medical complications. Strength in both upper extremities is 5/5. Strength in lower extremities, back extensors and abdominals is 0/5. He has no complaints of pain. In sitting he presents with a flexible posterior pelvic tilt, flexible increased thoracolumbar kyphosis and fixed bilateral plantarflexion contractures (unable to dorsiflex ankles beyond neutral). Key anatomical measurements include hip width of 16", upper thigh length of 18" and buttocks to axilla of 20".

John is modified independent in dressing and bathing with adaptive equipment. Weight shifts are modified independent using his upper extremities to perform a “push-up” in his wheelchair. John currently uses a K0005 manual wheelchair for all of his mobility needs and is independent for propulsion in all environments of typical use. He has just started residency training in medical school and needs to be able to perform clinical evaluations of his patients. However, he is unable to do so since the examination tables at the hospital are not height adjustable and are too high for him to access from a sitting position in his wheelchair. John was referred by his physician and vocational rehabilitation counselor for an evaluation for a manual standing wheelchair. He needs a system that will meet his needs in different clinical settings as well as in his home. The goals for John are to be able to (1) perform a clinical medical evaluation in a standing position; (2) move around in a wheelchair at work and at home and; access work surfaces and cabinets from a wheelchair.

John had an opportunity to trial a Helium manual standing wheelchair while at his work. He demonstrated independence in transitioning from sit to stand using the manual standing feature of the wheelchair. He was able to move from place to place throughout the clinic by propelling with his upper extremities in sitting and was able to achieve a standing posture when needed for function. He did, however, find that when he transitioned to a full standing position in the wheelchair that he was too high for some of the examination tables and beds. To be fully functional within the clinic, he needs to be able to achieve variable heights (partial standing).

John also had a variety of issues with this particular demo wheelchair. The 18”seat depth was too long, causing pressure to the back of his knees and a tendency to slide into a posterior pelvic tilt, especially when transitioning from stand to sit. The 14” back height was too low, resulting in poor trunk balance and a feeling of instability. The Varilite Evolution cushion was too thick and changed the relationship of his knee joints with the pivot point of the wheelchair. This caused shearing during transitions from sit to stand. The demo chair had no armrests and no anterior trunk support, which contributed to his feeling of instability when in standing. And the 15°open seat to back angle positioned him in a minimal recline, which limited his upper extremity reach.

A standing frame would not be an appropriate option for John, since it is a stationary device that would not allow him to move about his work environment. In addition, the components of the standing frame in front of his knees and torso would significantly limit the potential reach of his upper extremities. The Helium manual standing wheelchair did allow him to move independently throughout his environment at work, at home and throughout the community, but also allowed him to assume a standing posture at any time as needed. To address the issue of being too high for access to some of the exam tables/beds, the Helium manual standing wheelchair can be ordered with 400 Newton gas struts to allow John to be lifted and safely supported in partial standing as opposed to full standing. This will allow him to perform his clinical evaluations and improve reach and access at various heights.

While the primary purpose of standing for John is to provide improved reach and accessibility to his patients, the standing feature will also help to control his lower extremity spasms, provide a means for full pressure redistribution to protect his skin, and help to prevent further decrease in ankle range of motion.

The following recommendations are made based on the trial wheelchair.

- Helium manual standing wheelchair with 400 Newton struts to lift John into full standing position and also support him at different heights of partial standing
- Adjustable back height of 16-19" to provide stability and promote more erect posture both in standing and sitting.
- A 16" seat depth to eliminate pressure to the back of the knees and to decrease the tendency to pull into a posterior tilt particularly when moving from standing to sitting.
- A 16" x 16" low profile ROHO cushion. The pressure distributing material will reduce shear forces and protect the skin during movements while sitting in the wheelchair and during sit to stand transitions. The low profile of the cushion will keep John lower in the wheelchair to improve alignment of the hip and knee joints with the wheelchair pivot points. This will maintain proper alignment of the postural supports and reducing shear forces.
- Body point elastic chest strap SP110L to support the trunk in a stable, erect and midline position while standing
- Armrests for trunk stability and reaching while standing
- Medium knee blocks to hold the knees in extension while moving into standing and to distribute pressure over the knee while standing
- Backrest angle of -6° to improve standing posture and balance as well as upper extremity reach

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Helium- Standing MWC Case Example

Penny J. Powers PT, MS, ATP
Pi Beta Phi Rehab Institute
Vanderbilt Medical Center
Nashville, TN

"Tim" is a 40 year old male with a diagnoses of Multiple Sclerosis (diagnosed 1984), paraplegia, and low back pain secondary to degenerative arthritis of the lumbar spine. He has also been experiencing pain in both shoulder joints. Tim reports that he is unable to stand or walk and depends upon a wheelchair for all of his mobility. He states he has been using a wheelchair full time since 1999.

Tim is newly married with 2 young step-children, is highly motivated and is working toward sustaining the best health status that he can possibly achieve with maximum level of independence. He is gainfully employed in the Dept of Safety and provides computer/IT support for the Sheriff's Department. Although he works part of the day at a desktop computer, his responsibilities also require him to move throughout the office, providing IT support and consultation for internal employees at multiple work stations and locations. At home, Tim shares responsibilities of home management, cooking, cleaning, laundry and child care with his wife who also works full time.

Current Equipment
Tim currently uses a Quickie GT (K0005) high strength ultralightweight manual wheelchair. He reports that in this wheelchair he is often unable to reach objects and access cabinets, shelves and other surfaces to accomplish all of the tasks that he now needs to do at his job and at home. Many of those that he can access require overhead reaching and lifting, which has caused increasing pain in both shoulders. In addition, he is experiencing more frequent back pain with prolonged sitting that is interfering with his ability to complete tasks at work and at home. However, he is reluctant to take pain medications due to potential side effects that would interfere with this his ability to complete job responsibilities. He has been referred by his physician and vocational rehab counselor for evaluation for a standing manual wheelchair.

Goals from evaluation:
1. Obtain a standing MWC that is appropriately configured such that Tim can independently perform standing weight bearing activities for completion of ADLs and IADLs at home and at work, as well as for therapeutic benefits and for pain management.
2. Demonstrate safe and effective use of standing manual wheelchair in a variety of settings
3. Demonstrate ability to provide care and maintenance for standing manual wheelchair

Seating and Mobility Evaluation Summary
Tim is non-ambulatory and has used a wheelchair full time since 1999. He is independent in propulsion throughout all of his typical environments. He is able to transfer independently with a depression type transfer or a sliding board. His symptoms primarily affect his lower extremities with good upper extremity active range of motion, strength and coordination. Tim has significant extensor spasticity affecting primarily his trunk and lower extremities (3+ Modified Ashworth Scale) resulting in pain. Tim has also developed degenerative arthritis of his lumbar spine that causes him pain with prolonged sitting. Evaluation of his shoulder pain demonstrates that this is exacerbated by overhead reaching and lifting.

Equipment Trial Results

Tim trialed a Helium standing MWC with gas struts that allowed for an independent passive sit to stand transition. He was successfully able to use this MWC both at his home and workplace, as well as in the clinic. In the clinic, he demonstrated competence in his ability to position himself appropriately, don safety features and use his upper extremities to control the sit to stand function. Tim reported immediate improvement in his low back pain and stress when he was able to frequently alter his position by standing. At home, he was able to use the standing MWC in the bathroom for self care including voiding, shaving and dental hygiene. He was able to move throughout his home and access all objects and surfaces needed while he contributed to meal preparation and home management activities such as laundry and ironing. At work, he was able to move from location to location and reach and access objects and surfaces necessary to complete his job responsibilities. He was able to assume the standing position and perform these activities without complaints of pain or fatigue.

Rationale for Equipment

The ability to stand allowed Tim to more easily and efficiently complete the tasks required of him both at home and at work. The ability to reach objects and access cabinets, shelves and other surfaces from a higher position also greatly decreased the stress and strain on his upper extremities that was exacerbated by overhead reaching and lifting. This reduced his current shoulder pain significantly and will help to preserve his shoulder joint integrity and prevent further damage. When Tim was provided with the ability to frequently transition from sit to stand and to assume a prolonged standing posture throughout the day, he experienced decreased back pain. Standing allowed him to “off load the interverterbral disks”, as advocated by his orthopedic physician, with a non- invasive and non-pharmaceutical intervention.

A dedicated stander was ruled out as an option since it would not meet Tim’s need to move about from place to place and to stand at various locations throughout the day in the course of his routine activities at home and work. Tim must be able to move throughout the office environment independently to work at different work stations and he must be able to move from room to room in the house to complete home management and child care. A stationary stander would require multiple transfers into and out of the device and the assistance of one or more individuals to move the stander from location to location.

Any other type of manual wheelchair (K0001, K0003, K0004, K0005 or custom made to measure K0009) was also ruled out since there are no manual wheelchair bases that can accept a standing feature as an add-on and no separate standing systems that can be added on to a manual wheelchair base. The only systems available are frames that are totally integrated with the standing features; the 2 features cannot be separated. With the integrated system, Tim is able to meet his responsibilities at work and at home, manage his back and shoulder pain and use measures that can help to prevent further joint damage and injury.

Recommended Equipment:

Permobil Life Stand Helium, rigid frame, 17.5" x 18"- blue, gas struts (500N) - this chair is a manual wheelchair with a standing function. The passive assist to stand is achieved by gas struts that provide the mechanical energy/force to lift the individual while allowing the hips and knees to extend fully into the standing posture.

Standing Manual Wheelchairs – Evidence Summary

Evidence related to the benefits of standing manual wheelchairs is divided into two closely related, yet distinct topic areas. The first involves evidence related to the many benefits of standing as a posture or position. Much of the investigation into the benefits of standing is not specific to the technology used to support standing; i.e. the studies investigate the benefits of the posture or position itself, rather than the technology that allowed a person to attain and maintain a standing position. A related issue is dosage of standing; that is how often and for how long do individuals actually stand and what is their overall level of function and satisfaction with the technology that enables them to stand.

There has been a significant amount of research into the benefits of standing for wheelchair users, although the conclusions possibly are complicated by great diversity in both the mechanisms of achieving and maintaining standing and the resultant "dosages" of the standing. There is overall agreement that there are many clinical, psychosocial, and vocational benefits of being able to achieve and maintain this posture (Kreutz, 2000), however the details of how much or how long individuals should stand to achieve these benefits is less clear. There are certainly pressure redistributing benefits achievable through use of a wheelchair standing feature. In contrast with other weight shifting systems such as tilt and recline systems, a standing posture offers maximum load reductions from both the seat and the back support of the wheelchair (Sprigle, Maurer, & Soneblum, 2010). The standing system also allows the user to perform an effective weight shift while maintaining a functional position and horizontal gaze. This allows him/her to continue to engage in daily activities while adhering to a regular, frequent and effective pressure redistributing routine. Tilt systems relieve loads from the seat, but increase loads on the back support and require the individual to tip back in space. Recline systems also reduce loads on the seat by transferring weight at least partially to the back support, but require the individual to assume a supine or nearly supine posture . Tilt and/or recline require the individual to periodically and possibly frequently disengage from his/her activities in order to adhere to an effective pressure redistribution routine.

Additional potential benefits attributed to standing include: improving bladder and bowel function, reducing urinary tract infections, increasing range of motion, reducing excessive spasticity, increasing bone mineral density in the lower extremities, and improving cardiopulmonary and gastrointestinal functions (Kreutz, 2000). Many of these benefits are reported in research by the scientists monitoring them or through self report (Dunn et al., 1998). Although continued research is needed for further specification of dosage requirements to achieve these benefits, the evidence that there are benefits is substantial (Glickman, Geigle, & Paleg, 2010).

One of the most powerful advantages of standing manual wheelchairs is in offering the dual benefits of (1) mobility in a manual wheelchair, with all of its maneuverability and ease of use benefits, and (2) easy access to attaining and maintaining a supported standing position. This standing position can be achieved without the need to transfer out of the wheelchair. This allows a user to have greater ability to utilize this feature throughout the day. This advantage likely leads to better adherence to a routine schedule of standing, which was confirmed through a systematic effort to monitor the use of a wheelchair standing system (Shields & Dudley-Javoroski, 2005). This research was performed with one user and should be validated through further research, but it does confirm that access to this feature on a wheelchair allowed a user to access the system multiple times per day or week for shorter bursts of time. This will facilitate participation in activities of daily living in a home environment or vocational activities in a work environment. A more commonly used method of documenting use of standing systems is through self report surveys of individuals who have these technologies. In one such survey, users reported using their systems 3 -4 times per week and reported multiple health and function related benefits (Eng et al., 2001).

Standing Manual Wheelchair References:

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Evidence Review

A literature search prepared by the American Physical Therapy Association (APTA) August 31, 2011 for a similar project was used as a basis for this project evidence review and supplemented with more recent publications, and known gray literature where available. The original APTA literature review identified a total of 495 articles inclusive of a broader search than required for this K0009 review.

Dates:

A review of the literature was undertaken for the 10 years prior to September 2011. The search was focused over the past 10 years but key publications older than 10 years or published after 9/2011 were included where applicable. Dates of articles included ranged from 1998-2011.

Search Terms in various combinations included:

Activities of Daily Living[MESH]
Cost or Costs
Cushion
Equipment
Equipment Design[MESH]
Outcome
Outcome Assessment (health care)[MESH]
Position or Positioning
Posture
Powered
Pressure Ulcer
Prevention
Seat or Seating
Shoulder
Skills
Tire
Training
Treatment outcome [MESH]
Tyre
Wheelchair or Wheelchairs
Quality of life[MESH]
Wheeled mobility for special dx (progressive neurological dx)
W/C components
Skin Protection/pressure ulcer prevention
Shoulder protection
Wheelchair skills training
Cushion properties
Custom seating/positioning
Functional needs
Mobility related to ADLS
Eval/outcomes measures
Changes in Function with equipment
Cost effectiveness

Databases:

CINAHL Plus with Full Text
Cochrane Database of Systematic Reviews
Health Technology Assessments
PubMed
Google (for resources from the government, universities, and non-profits)
APTA's library catalog
RESNA Annual Conference Proceedings (http://www.resna.org/conference/proceedings/index.dot)
RESNA Position Papers
Hooked on Evidence
PEDRO
National Rehabilitation Information Center
AHRQ

Procedure:

All of the titles and abstracts of the 495 articles identified in the APTA search were reviewed. Articles that did not pertain to the K0009 manual wheelchair categories, equipment features or performance were eliminated leaving 107 remaining from the original list. Seven new articles were identified, resulting in a total of 114 articles of which 45 were found relevant and included in the evidence reviews for this project.

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