VA | U.S. Department of Veterans Affairs

# Clinical Limits of Use Tool (CLOUT)

## for Wheeled Mobility Devices


Developed by
**VA National Center for Patient Safety**
and
**The Human Engineering Research Laboratories**

A Partnership Among
**VA Pittsburgh Healthcare System**
**University of Pittsburgh**
**University of Pittsburgh Medical Center**



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NCPS VA National Center for Patient Safety
*Safer Systems • Safer Care*

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# Preface

**Rationale**

The Veterans Health Administration (VHA) within the Department of Veterans Affairs (VA) purchases medical devices and assistive technologies to maximize the health, function, quality of care and quality of life for Veterans. While safety is a primary consideration when coordinating and delivering patient care with incorporation of healthcare technologies, there is a paucity of scientific evidence on safe and effective use of medical devices, industry standard regulations have not been well developed and/or enforced, and the limits of use of these devices have not been sufficiently explored. To support the VA to maximize the quality of service for Veterans while also ensuring that medical devices meet safety and performance expectations, an internally developed tool, with a focus on purchasing for safety, must be established. Development of this tool will provide a framework to identify device limits of use that will guide clinical care, shape VA expectations for purchasing, and guide procurement personnel to facilitate comprehensive evaluation of products against established specifications. Patient safety will be prioritized when all stakeholders - including Veterans, VA professionals and vendors - understand the recommended process for evaluating and determining limits of use for devices provided by VA.

**Mission**

The mission is to provide a clinical limits of use tool (CLOUT) to evaluate wheeled mobility devices across a range of design and performance factors related to the Veteran, the Veteran's intended activities, and the Veteran's environment. This will allow clinicians to better understand the risks associated with different wheeled mobility devices and will guide clinicians in the selection of the most appropriate devices for each Veteran. For new and emerging products, the tool will provide guidance to VA stakeholders and external stakeholders (e.g., manufacturers and suppliers) on what factors will be used to determine whether the product is safe, performs to expectations, and is potentially appropriate for Veterans.

**Scope**

This document addresses wheeled mobility devices for adults, which include commercially available wheelchairs (manual and electric power), scooters, and other devices that are intended to provide at least temporary mobility using a wheeled base in either a seated and/or standing position. Standard wheeled mobility accessories (e.g., power seating functions, or anti-tip systems) are included within the scope. Custom accessories, such as custom molded seating systems and wheeled mobility devices for children, are beyond the scope.

**Audience**

The primary intended audience is clinicians within the VA who are providing or being trained to provide wheeled mobility devices to Veterans. A secondary audience includes stakeholders within the VA involved in procurement and management of wheeled mobility devices (e.g., prosthetics agents, contracting personnel, biomedical engineers, and technicians). Another secondary audience includes stakeholders outside the VA such as wheelchair designers, manufacturers, and suppliers to help them better understand the factors that are used to provide the optimal wheeled mobility device for the Veteran.

**CLOUT Components**

CLOUT consists of several components: a literature review that provides background evidence of the limits of use of wheeled mobility devices, regulation and coding requirements that describe product quality and safety, instructions for using the CLOUT documents, and product category descriptions that include visual dashboards. Product category descriptions for manual wheelchairs, power wheelchairs, and scooters describe features, usage scenarios, performance expectations, limits of use, and limits of use mitigation. Three dashboards (for manual wheelchairs, power wheelchairs and scooters) visually present product categories side by side, and indicate a list of device features and whether a feature is provided, not provided, or provided for a limited selection of products in each category.

**Limitations of This Document**

This document provides guidelines on the limits of use for wheeled mobility devices based on published research and expertise gained from a committee who have designed, tested, and provided wheelchairs for many years. This document is meant to support, but not replace, appropriate clinical provision of wheeled mobility, which includes a comprehensive assessment, prescription, product preparation, delivery and follow-up, and comprehensive education and training. Similarly, this document provides only an overview of the limits of use of different devices that are currently available. Some devices may be more or less limiting than portrayed here; it is the responsibility of the service provision team to gauge the limits of each wheeled mobility device before, during, and after provision to ensure that a safe and reliable device is provided. Finally, research and best practices are continually changing, so individuals using this document should seek out the most recent resources to learn about emerging concepts. **The CLOUT process is dynamic and constantly evolving. Therefore this document requires update on a regular basis as new technology becomes available.**

**How to Use This Document**

The entire document should be read at least once from beginning to end to provide the foundational information for appropriate provision of wheeled mobility devices. After a complete reading, each numbered section (1-6) can be referenced independently to provide guidance during day-to-day services and to support the selection and provision of appropriate and safe products.

## Acknowledgments

The *Clinical Limits of Use Tool (CLOUT) for Wheeled Mobility Devices* was developed by the U.S. Department of Veterans Affairs (VA) National Center for Patient Safety (NCPS) and the Human Engineering Research Laboratories (HERL). A special thank you is extended to the authors and contributors who created this tool.

**VA National Center for Patient Safety**

**Author:**

Kendra Betz, MSPT, ATP, Clinical Program Specialist

**Contributors:**

Katrina Jacobs, MS, CCE, Biomedical Engineer

Tandi Bagian, MSE, Director, Human Factors Engineering Division

Deborah Royal, VHA-CM, Visual Information Specialist

**Human Engineering Research Laboratories**

**Authors:**

Brad E. Dicianno, MD, MS (Clinical Lead); Medical Director and COO, HERL

Jon Pearlman, PhD (Technical Lead); Associate Director for Product Innovation and Translation, HERL

Rory A. Cooper, PhD; Director and CEO, HERL

Garrett Grindle, PhD; Assistant Director For Engineering, HERL

Benjamin Gebrosky; Testing Engineer, HERL

Patricia Karg, MS; Assistant Professor, Department of Rehabilitation Science & Technology, University of Pittsburgh

Mahender A. Mandala, PhD; Post-Doctoral Researcher, HERL

**Contributors:**

Mark R. Schmeler, PhD, OTR/L, ATP; Associate Professor, Department of Rehabilitation Science & Technology, University of Pittsburgh

Chad Evans, PT; Physical Therapist, VA Medical Center, H.J. Heinz Campus

Rosemarie Cooper, MPT, ATP; Director, UPMC Center for Assistive Technology

Joseph Ruffing; Communications Specialist, Department of Rehabilitation Science & Technology, University of Pittsburgh

# Contents

# 1 A Framework for Evaluating Limits of Use for Wheeled Mobility Devices



## 1.1 Purpose

Development of a Clinical Limits of Use Tool (CLOUT) requires a theoretical framework that grounds the tool in evidence-based research and best clinical practices. This section describes the published evidence that outlines scientific theory and research, clinical consensus, and clinical practice guidelines that serve as the basis of the development of CLOUT. As a result, this section can be used independently as a reference to understand how various features of wheeled mobility devices match the needs of the Veteran. The reader should gain an understanding that wheeled mobility devices are medical devices, and just like a prescription medication, have limits in the way they can and should be used and require an appropriate and comprehensive evaluation before prescription.

## 1.2 Overview

Best practices guide the essential steps in the provision of wheeled mobility devices. While the purpose of CLOUT is to fully describe the limits of use of various wheeled mobility devices, equipment recommendation and selection is only one step in the overall provision process of wheeled mobility devices, as defined by the Rehabilitation Engineering and Assistive Technology Society of North America (RESNA) Wheelchair Service Provision Guide.[1] It is important to note that provision of wheeled mobility devices involves many other steps, the thorough discussion of which is beyond the intended scope of this document. Briefly, the steps in the provision process according to the cited Provision Guide are: client assessment; equipment recommendation and selection; funding and procurement; product preparation; fitting, training and delivery; follow-up, maintenance, and repair; and outcome measurement. Limits of use can be associated

with any of the steps in the process, especially when involved clinicians and support personnel require additional education, experience, and support, when inadequate training is provided to Veterans on device configuration, maintenance, transfers, power wheelchair driving, manual wheelchair propulsion or equipment management, or when funding limitations or procurement processes limit access to optimal technologies.

CLOUT uses a framework to describe how devices are matched to the Veteran that is based on the International Classification of Functioning, Disability, and Health (ICF) model.[2] See **Figure 1**.

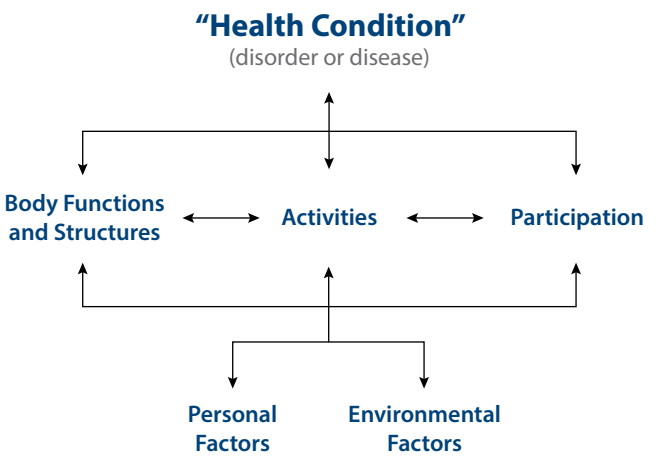


**Figure 1** The ICF Model (Credit: icfeducation.org)

The ICF model is used to define factors such as human body structures and functions, activities, participation, environmental, and personal factors that should be taken into consideration along with the appropriate regulatory and device specific factors when selecting a wheeled mobility device for a Veteran. In this document, we will refer to the "seating system" as the seat and back support, and additional "seating and positioning items" as after-market accessories that can be added or installed (e.g., headrest, lateral supports). Finally, "options and accessories to customize" the device (e.g., caster options, ergonomic push rims, high strength light-weight spokes) for each individual Veteran can enhance performance of the device in certain environments, improve comfort, or improve ergonomics for injury prevention.

Important clinical practice guidelines and research studies from the scientific literature are referenced to describe specific wheeled mobility device features, performance, and safety considerations. Integration of knowledge from the published literature with the ICF model and experience with testing and use of wheeled mobility devices by people with mobility impairments guides determination of limits of use for different products and circumstances.

# 1.3 Factors Defining Wheeled Mobility Device Use

The following sections define the critical factors that must be addressed for each Veteran requiring a wheeled mobility device. The features and limitations inherent to the wheeled mobility device can positively or negatively affect the Veteran; therefore, the association between Veteran needs and wheeled mobility device features must be clearly understood to support provision of optimal technologies. See **Table 1** for a graphical depiction of these relationships.

## 1.3.1 Human Body Structures and Functions Factors

**Postural support** is necessary for Veterans with impaired trunk control, for those who need stability of the trunk to functionally use the head or arms, or for those with postural asymmetries such as scoliosis and pelvic obliquity. Postural support can be achieved through customization of the seating system and front rigging (by configuration or adjustment), and by adding seating and positioning items such as lateral supports. This can also be facilitated through use of manual- or power-operated seat functions such as tilt and recline.[3]

**Preservation of tissue integrity** is an important consideration when matching a device with a Veteran who may be at risk of soft tissue compromise, such as injury from shear or pressure. Veterans with paralysis and/or loss of sensation from conditions such as spinal cord injury or diabetes, for example, may experience soft tissue injury when transferring into, out of, or when seated in a wheeled mobility device. If a Veteran is considered to be at risk of soft tissue compromise, several features of the device must be considered. Specially designed cushions must be used to provide a pressure reducing surface between the Veteran and the device.[4] While many types of pressure reduction cushions are available, not all wheeled mobility devices accommodate addition of these highly specialized cushions. The seat back material, structure, height and adjustability affects posture, which in turn affects seat interface pressures and tissue integrity.[5,6] Ability to change seat position, such as recline or tilt features, whether manually operated or added as a power seat function, can also reduce pressure at the seating surface or can increase risk for shear if used improperly.[3,7] Adjusting the front rigging can also be beneficial for managing pressure at the sitting surface.

**Joint preservation, range of motion (ROM) accommodation, and tone management** may be important for Veterans who experience or who are at risk for repetitive strain injury of the arms or those with spasticity or limited joint range of motion. The interface of the device with a Veteran's body while the joints move, while the device moves, or even while the device and Veteran are stationary, can affect the tone in the muscles or the long term health and integrity of the joint.[8] It is important to understand the intended duration of use, as some wheeled mobility devices are intended only for temporary or intermittent use, while others are intended for long term or permanent use. Also, it is important to understand whether a manual wheelchair is intended to be attendant propelled or propelled by

the Veteran, and whether the device can be moved with arm propulsion, foot propulsion, or both. Device weight affects the load experienced at the shoulder during wheelchair propulsion.[8,9] Adjustability of the rear wheel axle in three planes affects shoulder ergonomics and joint position when propelling the chair with the pushrim.[8,9,10] Likewise, when other propulsion methods are used, such as an arm crank or lever, adjustability of these interfaces also affects ergonomics and joint position. Moreover, adjustability of the device itself, such as seat width, also has an effect on ergonomics and joint position. Features that reduce propulsion frequency or repetition, such as power assist devices, increased rear wheel size, add-ons, cranks, and levers, can reduce the overall number of repetitions a Veteran must conduct in order to move the device over a given distance.[8,11] Finally, many seating adjustability options such as seat functions, adjustable leg rests, extent of front and rear seat height adjustments, front rigging angle, foot plate position, and other options (i.e., center mount footplate on center post vs. bilateral swing-away with independent foot plates) can affect the tone in the muscles[3,7] or joint position.[8,10,12] Options and accessories to customize the device for each individual Veteran can improve ergonomics, and efficient and safe management of the device, thereby preserving joint integrity.

**Preservation of bone integrity** is an important consideration for Veterans at risk of losing bone mineral density related to medical diagnoses and/or anticipation of a long term seated position. Standing features incorporated into some devices allow the Veteran to achieve and maintain an upright position to load the long bones of the lower limbs along the axial plane to various extents.[13,14] The risk of lower extremity fracture is potentially decreased with early and consistent standing, while the risk of fracture may be increased when standing is initiated later or intermittently, especially when bone density is compromised.

**Comfort** is related to many device factors, especially those that preserve body movement within the wheeled mobility device. Positioning and postural support features impact Veteran position, fatigue, sitting tolerance, and overall comfort.[3,7] A wide range of seating systems and seating and positioning items exist, but not all devices can accommodate all systems or features. Some common items used for comfort include adjustable seats or backrests, alternate or after-market back supports, seating systems with dynamic movement, seat functions, cushions, lateral supports and head supports.

Many **other physiological processes** of the body are affected by mobility devices. Certain aspects of the device may mitigate or worsen these processes. Various functions of the device can be used to manage orthostatic hypotension, visual orientation, speech, alertness and arousal, respiration, bowel and bladder function, and edema.[3,7]

**Ventilators** are necessary for those with respiratory failure, sometimes a comorbidity for those with significant mobility limitations. The requirement for a ventilator must be carefully considered when identifying potentially appropriate wheeled mobility options as they can be accommodated only on some mobility devices. With some progressive disorders (e.g., Amyotrophic Lateral Sclerosis (ALS)), a ventilator may not be immediately indicated but may be anticipated as a future intervention and must therefore be supported by the wheeled mobility device provided.

**Body weight** of the person requiring a wheeled mobility device is another important consideration. The weight capacity of wheeled mobility devices is specified for different options and must match the Veteran's needs to support expectations that the device is safe and performs optimally over time. Some people require heavy duty or extra heavy duty wheeled mobility devices that are reinforced to accommodate body weight.

### 1.3.2 Activities and Participation Factors

**Mobility** of a Veteran who uses a wheeled mobility device includes many considerations. First, certain aspects of the device can affect the Veteran's ability to transfer in and out of it. Transfer ability can be affected by seat height.[15] Various seat functions can also change seat position in other ways that improve biomechanical positioning to prepare the Veteran for an independent transfer or to assist caregivers in transferring the Veteran.[3,7] Removing some seating and positioning items (e.g., arm supports and clothing guards) can support efficient transfers. Alternatively, other seating and positioning devices like transfer aides (e.g., transfer handles, power transfer devices) can be added to some devices to facilitate transfers. Requirements of transferring from the device to and from a vehicle should also be considered when appropriate. A second aspect of mobility is the actual act of getting from one place to another in the device through interfacing with the device. Power wheelchair driving ability, for example, depends on a number of factors including programmability options of the controller, and the Veteran's ability to use a control interface (e.g., joystick, switch, alternative controls). Manual wheelchair propulsion ability is intimately related to the ergonomics of wheelchair propulsion and the ability to use the pushrim, which is described more fully above. In any mobility device, adjustability of the seating system allows the Veteran to be positioned in a way such that their ability to control the device is optimized.

**Self-management**, or the ability to carry out important tasks such as activities of daily living (ADLs), can be affected by many aspects of the wheelchair, particularly how the Veteran is positioned and supported in the device. Adjustability of the seating system (the back support and seat plane) not only improves the Veteran's position as it relates to moving the device, but also as it relates to carrying out certain ADLs, such as elevating a Veteran's height in order to reach objects important for ADLs,[15] or lying in a recumbent position within a wheelchair in order to manage the bladder or dress.[3,7]

**Community participation** while using a wheeled mobility device depends on a number of factors. Some of these factors are intimately related to the environment, which is described more fully below. The ability of a Veteran to participate in meaningful activities such as conducting ADLs in the community, communicating with other individuals, or participating in employment or educational activities are related to seat height,[15] ability to change seat position with other seat functions,[3,7] and ability of the device to interface with electronic communications devices (e.g., smartphone, augmentative and alternative communication, or Bluetooth capability to operate computers or environmental control units).

**Transportation** in personal vehicles and/or public transit options must be closely considered when determining the optimal wheeled mobility device. Those who cannot transfer to a vehicle seat, or choose not to due to medical or safety reasons, need a mobility device that can be used safely as a seat in a motor vehicle.[16] The mobility device should be compliant with the voluntary standard, RESNA WC-19 *Wheelchairs used as seats in motor vehicles,*[17] and after-market seating systems should be compliant with voluntary standard, RESNA WC-20 *Wheelchair seating systems for use in motor vehicles.*[18] Those who are able to transfer to a vehicle seat should do so for optimized safety while driving or traveling as a passenger. When the wheeled mobility device is not used as a seat in the motor vehicle, it must be secured to the vehicle or disassembled and stowed, in which case portability is an important factor.

### 1.3.3 Environmental Factors

Both indoor and outdoor environments can limit the use of all types of wheeled mobility devices. Indoor environments can limit use due to limited physical space required to maneuver (e.g., narrow doorways or small rooms), soft surfaces such as high-pile carpet, slippery surfaces such as a wet bathroom floor, and thresholds and stairs. Outdoor environments can limit use due to soft/slippery surfaces, slopes, and uneven terrain. The limitations that a certain environment may present also depend on the type of device being used. For instance, carpet can pose a limitation for a manual wheelchair user, but does not typically limit power mobility device use indoors. Alternatively, a small curb outdoors can completely restrict access for a power wheelchair user, but a manual wheelchair user may be able to easily negotiate the curb by doing a "wheelie," a skilled maneuver that elevates the front casters while balancing on the rear wheels. These examples illustrate why it is critical to understand the types of environments the Veteran will encounter to guide the proper selection of the wheeled mobility device.

In addition, the type of environment in which a device is used may have implications on the reliability of the device. Devices used in adverse outdoor environments, such as rough terrain, inclement weather, and areas where there is a significant amount of debris (e.g., dirt, gravel, and muddy roads) require a device designed for these conditions. In 2008, the World Health Organization published a Guideline document on wheelchairs[19] that argued that standards for wheelchairs (RESNA and International Organization for Standardization (ISO))[20,21] lacked the necessary rigorous tests to evaluate whether wheelchairs would survive in adverse environments. Unfortunately, very little progress has been made since 2008 to address this issue. Therefore, when clinicians learn that a Veteran will use their device in adverse environments, they should be diligent with product review, highly selective of product features, and attempt to gather evidence based on consumer experience that the product has proven to be reliable in those conditions.

Data gathered from power wheelchair users about outdoor driving suggested that the five most difficult driving conditions to avoid were uneven terrain (where one wheel is off the ground), soft sand, ice, mud and cross-sloped terrain. Alternatively, the five easiest driving conditions included dry grass, heavy carpet, ramps, driving at night, and traversing curb-cuts.[22,23] Power wheelchair users can also find it particularly challenging to maneuver indoors through narrow doorways and hallways, and in otherwise tight spaces, such as a bathroom. Determining the difficulty of driving conditions can aid in the proper selection of the product. Although similar data have not been published for manual wheelchair users, a general principle applies related to terrain. Soft terrain will make it more difficult for a manual wheelchair user or a caregiver to propel the device. Thus, soft terrain may impair mobility, and for a self-propeller may put undue strain on the upper limbs that could accelerate repetitive strain injuries.[8]

Both manual and power wheelchairs are susceptible to tip-overs, which has been cited as the most frequent wheelchair-related injury.[24] Tip-overs can occur due to a steep slope or if a Veteran impacts an obstacle or soft terrain while driving. Since tip-overs represent an extreme safety hazard with the potential for Veteran injury and/or wheelchair damage, wheelchair skills training must be provided to both manual and power mobility device users. Wheelchair skills training has been demonstrated as effective for facilitating skill acquisition in varied learning and physical environments.[25,26]

### 1.3.4 Personal Factors

Certain factors associated directly with the Veteran, or choices related to the aesthetics of the device, may impact self-image, acceptance of disability, or ability or willingness to use the device. These personal factors therefore may impact the activities that one wishes to perform, or the ability to use the device in certain environments. The personal factors that need to be considered during the assessment fall outside the scope of this document, but deserve mention here because of the importance to the Veteran. Gender and age, for example, are personal factors that are known to influence the design of products.[27] It is important to realize that most wheelchairs have been designed for men, and do not always accommodate the needs of women. For example, the anthropometrics of women differ from those of men and can therefore affect the fit of a device. Also, some devices can accommodate changes to the body that occur during pregnancy, while most cannot. Certain personal choices regarding the aesthetics of the device (i.e., the ability to "personalize" the device), such as device color, may have more importance to some Veterans than others.

**Table 1** Matching Veteran Needs from ICF Domains to Wheeled Mobility Device Features

| Features | | Body Structures & Functions Factors | | | | | | | | | | Activity Factors | | | | | | | | | | Environmental Factors | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Postural Support | Preservation of Tissue Integrity | Joint Preservation | ROM Accommodation | Tone Management | Preservation of Bone Integrity | Comfort | Physiologic/Medical Management | Ventilator Support | Overweight/Obesity Accommodation | Propels MWC① with upper Limb(s) | Propels MWC① with Lower Limbs(s) | Performs Advanced MWC① Skills | Drives PWC② & Operates Seat Functions | Drives with Alternative Controls | Reaches from WC③ | Transfers | Uses WC③ as Seat in Motor Vehicle | Stows Wheelchair in Vehicle | Indoor Mobility Home | Indoor Mobility Community | Outdoor Mobility Built | Outdoor Mobility Unbuilt | Outdoor Mobility Inclement Weather | Outdoor Mobility Extreme Terrain |
| **Manual & Power Wheelchair Features** | Seating System Customizable | ■ | ■ | ■ | ■ | ■ | | ■ | ■ | | | ■ | ■ | ■ | ■ | ■ | | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | |
| | Accommodates Ventilator | | | | | | | | | ■ | | | | | | | | | | | | | | | | |
| | Intended to Accommodate Seating/Positioning Items | ■ | ■ | ■ | ■ | ■ | | ■ | ■ | | | | | | | | | ■ | | | | | | | | |
| | Front Rigging Position Customizable | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | | | ■ | | | | | ■ | | | | | | | | |
| | Adjustable Seat to Floor Height | | | | | | | ■ | | | | | ■ | | | | ■ | ■ | | | | | | | | |
| | Options & Accessories to Customize | ■ | ■ | ■ | ■ | ■ | | ■ | ■ | | | | | | | | | | | | | | | | | |
| | Supports Tilt in Space | ■ | ■ | | | | | ■ | ■ | | | | | | | | | ■ | | | | | | | | |
| | Supports Standing | | | | | | ■ | ■ | | | | | | | | | ■ | | | | | | | | | |
| | Supports Seat Elevation | | | | | | | ■ | | | | | | | | | ■ | ■ | | | | | | | | |
| | Heavy Duty or Extra Heavy Duty Options | | | | | | | | | | ■ | | | | | | | | | | | | | | | |
| | Compliant with WC-19 and WC-20 | | | | | | | | | | | | | | | | | | ■ | | | | | | | |
| **Manual Wheelchair Features** | Rear Wheel Position Customizable | | | ■ | | | | ■ | | | | ■ | | ■ | | | | ■ | | | ■ | ■ | ■ | ■ | ■ | ■ |
| | Rear Wheel Removable | | | | | | | | | | | | | | | | | | | ■ | | | | | | |
| **Power Wheelchair Features** | Expandable Controller/Alternative Controls | | | | | | | | | | | | | | ■ | ■ | | | | | | | | | | |
| | Multiple Power Option | ■ | ■ | ■ | ■ | ■ | | ■ | ■ | | | | | | | | | | | | | | | | | |
| | Single Power Option | | ■ | ■ | | | | ■ | ■ | | | | | | | | | | | | | | | | | |
| | Drive Wheel Suspension | | | | | | | | | | | | | | | | | | | | | | ■ | ■ | ■ | ■ |
| | Group 1 Performance | | | | | | | | | | | | | | | | | | | | ■ | | | | | |
| | Group 2 Performance | | | | | | | | | | | | | | | | | | | | ■ | ■ | ■ | | | |
| | Group 3 Performance | | | | | | | | | | | | | | | | | | | | ■ | ■ | ■ | | | |
| | Group 4 Performance | | | | | | | | | | | | | | | | | | | | ■ | ■ | ■ | ■ | ■ | |
| | Beyond Group 4 Performance | | | | | | | | | | | | | | | | | | | | | | | | | ■ |

① **MWC** = Manual Wheelchair

② **PWC** = Power Wheelchair

③ **WC** = Wheelchair

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# 2 Product Quality and Safety



## 2.1 Purpose

Limits of use of wheeled mobility devices can be defined through technical and performance standards combined with a comprehensive clinical evaluation. This section describes the applicable technical and clinical processes that can be used to establish CLOUT. As a result, this section can be used independently as a reference to understand these processes and the related policies and coding schemes.

## 2.2 Regulations for Wheeled Mobility Devices

Regulations relevant to wheeled mobility devices are developed and enforced to help assure the devices are safe for the Veterans and caregivers. It is important to be aware of the types of regulations and understand how they are applied to different products being purchased by the VA. The US Food and Drug Administration (FDA) regulates all medical devices in the US, including wheeled mobility devices. Manual wheelchairs are considered Class I (lowest risk) medical devices and power wheelchairs and scooters are considered Class II (moderate risk) medical devices. Originally, stair-climbing wheelchairs were considered high risk (Class III), but based on relatively few injury reports, they were reclassified to Class II.[28] Higher classifications are tied to more stringent production standards,[29] and are often linked to more extensive product testing requirements.

Class 1 manual wheelchairs only need to be shown to be 'substantially equivalent' to products on the market through the 510(k) process, and the FDA recommends but does not require the products to be tested to identified consensus standards. Class II power wheelchairs must be tested to the identified consensus standards to confirm product safety, and the test reports must be submitted to the FDA before the product is cleared for marketing.

## 2.3 Design and Performance Standards for Wheeled Mobility Devices

Standardized methods for testing wheeled mobility devices are developed by committees of technical experts coordinated through national and international standards bodies. The standards address design, performance and labeling requirements for wheeled mobility products. The technical standards are recognized by regulators (e.g., FDA) and purchasers (e.g., VA, Centers for Medicare and Medicaid Services (CMS), private insurance providers) as consensus standards, and incorporated into regulatory and purchasing processes to assess product safety. The Rehabilitation Engineering and Assistive Technology Society of North America (RESNA) coordinates a number of technical committees on behalf of the American National Standards Institute (ANSI), which publishes wheelchair standards, known as the RESNA American National Standards for Wheelchairs.[20] International standards are developed by the International Organization for Standardization (ISO), which publishes wheelchair standards as the ISO 7176 series.[21] Products may be tested to RESNA and/or ISO standards; both are acceptable and recognized by the FDA and CMS.

The RESNA wheelchair standards are national standards that apply to manual and power wheelchairs, scooters, and accessories for wheelchairs and scooters. The standards specify vocabulary, disclosure requirements for testing, and test methods including: stability while resting (static) or moving (dynamic) on sloped surfaces; wheelchair and seat dimensions; strength and durability of the device and components; flammability of upholstery; brake effectiveness; amount of energy or power used; maximum speed, acceleration and deceleration; obstacle-climbing ability; performance in adverse climates (e.g., rain, heat, cold); safety of the power and control systems; and electromagnetic interference with other devices. There are currently two volumes and nineteen sections of the RESNA wheelchair standards for manual and power wheelchairs, as listed in Section 2.7. Example test reports are provided in the Appendices.

RESNA wheelchair transportation safety standards exist for wheeled mobility devices that will be used as seats in a motor vehicle. The RESNA position paper on wheelchairs used as seats in motor vehicles emphasizes that those who cannot transfer to a vehicle seat, or choose not to due to medical or safety reasons, need a mobility device that can be used safely as a seat in a motor vehicle (i.e., one that has been crash tested).[16] A mobility device that will be used as a seat in a vehicle should be tested to and comply with RESNA WC-19, "Wheelchairs used as seats in motor vehicles." After-market seating systems (such as add-on back supports) should comply with RESNA WC-20, "Wheelchair seating systems for use in motor vehicles." Only pediatric wheelchairs are required to be crash tested by CMS. Other wheelchairs may have been voluntarily crash tested by the manufacturer. If compliance with transportation safety standards cannot be confirmed for a given product, the wheelchair should not be used as a seat in a motor vehicle. Equivalent international standards for wheelchairs used as seats in motor vehicles are ISO 7176-19, "Wheelchairs – Part 19: Wheeled mobility devices for use as seats in motor vehicles" and ISO 16840-4, "Wheelchair seating – Part 4: Seating systems for use in motor vehicles."

User manuals and order forms often note the weight capacity that was used for crash testing. The weight capacity used for crash testing is sometimes not equivalent to the maximum weight capacity noted for the device. This should not be a cause for concern during the prescription process, as compliance with the crash testing standard (WC-19) is sufficient to indicate the wheelchair can be used as a seat in a motor vehicle and will improve transportation safety for a user up to the maximum weight capacity of the device.

It is also important to confirm that the wheelchair tiedown and occupant restraint system (WTORS) utilized for wheelchair transportation has been tested to and complies with requirements outlined in RESNA WC-18, "Wheelchair tiedown and occupant restraint systems for use in motor vehicles" or ISO 10542-1, "Wheelchair tiedown and occupant-restraint systems – Part 1: Requirements and test methods for all systems. A list of products that meet transportation standards is posted by the University of Michigan Transportation Research Institute (UMTRI) at http://wc-transportation-safety.umtri.umich.edu/crash-tested-product-lists.

Technical standards provide several benefits, including product design and performance requirements; promotion of safer, more reliable and functional products; improved cost effectiveness; enhanced compatibility between products; and test methods leading to comparable, reliable performance data for more informed decisions. The following are important points of clarification about wheelchair consensus standards.

- The standards are voluntary, and unless required by regulators and/or purchasers, products are often not tested.
- Stakeholders should request and review test reports for all wheeled mobility devices being considered for purchase.
- Manufacturers should test their devices to the consensus standards to demonstrate objective measures of performance, durability and safety.
- Tests performed by independent test labs are preferred over tests performed by manufacturers because increased objectivity of test results is expected.
- Despite the regulatory framework and test methods for wheeled mobility devices, there is considerable evidence of quality and reliability concerns. Independent test lab reports indicate that some products that are required to pass the standards do not.
- Community-based studies have provided additional evidence that wheeled mobility devices break down frequently.
- Clinicians and stakeholders should understand, request, use and promote testing of wheeled mobility products to the standards.
- Clinicians and other stakeholders should be aware of contract and procurement requirements, and related regulations, so they can accurately assess and report when Veterans receive low-quality products.

## 2.4 Wheeled Mobility Device Quality Concerns

Testing laboratories (hereafter referred to as test labs) use the standards to assess and compare performance of products. Test labs are either owned and managed by manufacturers or owned by non-manufacturer entities and managed as independent test labs. Manufacturers use the results of standardized testing internally to assess and improve designs and manufacturing. Independent test labs will primarily perform contract testing for manufacturers, and in some cases, publish research studies about test results and comparisons of a variety of products. The standards can be applied to an entire wheeled mobility device, and/or be used to test specific components of the device (e.g., wheels or batteries). Results of testing can be used to support justification for prescription and procurement decisions.

Although the regulatory framework and test methods for wheeled mobility devices have been in place for several decades, there is considerable evidence of ongoing quality and reliability concerns. For instance, there have been a series of products tested to RESNA standards that indicate products do not pass the standards despite the requirements set by the FDA and purchasers such as the VA or CMS.[30-45] A retrospective analysis of these test results of 246 wheelchairs collected over a 16 year period (1992 – 2008) indicated that product quality is stagnant, and relatively low, since many chairs failed durability tests.[45] Community based studies have provided additional evidence that wheeled mobility devices breakdown frequently (about 50% suffer a breakdown every 6 months) that can cause adverse consequences.[46-49] These data suggest that FDA clearance alone does not guarantee that the product is safe and reliable. Further device evaluation, review of reported adverse events, and measurement of outcomes are required to help ensure wheelchairs are of high quality. Follow up with Veterans who have received a wheeled mobility device is important to gauge customer satisfaction, identify poorly performing products or features, and review safety concerns that must be addressed and potentially reported.

## 2.5 CMS Coding for Wheeled Mobility Devices

CMS categorizes wheeled mobility devices using codes established by CMS and its contractors according to the Healthcare Common Procedure Coding System (HCPCS). Although the VA provides devices that CMS does not, it is important to be familiar with these codes because they are used as reference within the VA procurement systems. CMS has developed mobility device codes (K codes and E codes) and coding requirements based on product features, performance, and occupant weight capacity. It is important to recognize that while an extensive list of specific codes is established, commercial products may not exist for every code.

CMS requires power wheelchairs to meet or exceed performance and durability criteria when tested to the RESNA standards. Power wheelchair categories defined by CMS specify criteria that a device must meet to be coded in a particular group. CMS HCPCS codes are assigned to power wheelchairs for adults within four main groups: Group 1 (K0813 – K0816), Group 2 (K0820 – K0843), Group 3 (K0848 – K0864), and Group 4 (K0868 – K0886). HCPCS codes for power wheelchairs for children are captured as Group 5 (K0890-K0891), but are beyond the scope of this document. CMS defines minimum requirements for each category (Group 1 through Group 4) for top end speed, driving range, obstacle height climbing ability, and dynamic stability on an incline. HCPCS codes are assigned to power operated vehicles (scooters) with two main groups, Group 1 (K0800-K0802) and Group 2 (K0806-K0808). Although CMS requirements are not referenced during the VA procurement process, because identical wheelchairs are sold to the VA and through CMS reimbursements, it is important for VA stakeholders to understand these performance expectations.

Some power wheelchairs do not meet all performance criteria specified for coding within a group. In this case, the K0898 code, "Power wheelchair, not otherwise classified" may be assigned. Other power mobility devices have exceptional capabilities or enhanced functions for mobility in particular environments (i.e., extreme outdoor terrain) that exceed Group 4 coding requirements. The K0899, "Power mobility device, not coded by DME PDAC (Pricing, Data Analysis and Coding) or does not meet criteria" is applicable. In all cases, clinical device testing in addition to review of RESNA test results is needed to fully understand the product features and limitations.

HCPCS codes assigned to manual wheelchairs are not by "group" or based upon performance requirements, rather codes are determined by product features. Some features are confirmed by objective laboratory testing to standards, such as device weight and weight capacity. Manual wheelchair HCPCS codes include K0001-K0009, E1161 (tilt), E1225-E1226 (recline option added to wheelchair), and E1038-E1039 (transport).

Several different types of accessories are available that add a power supply to a manual wheelchair. Power add-on options convert a manual wheelchair to a joystick controlled (E0983) or tiller controlled (E0984) power mobility device. Pushrim activated power assist wheels (E0986) provide power augmentation when a propulsive force is applied or power is activated by contact with the pushrim. When any power system is added to a manual wheelchair, it is expected that the performance and usability of the manual wheelchair is altered significantly. The combined manual wheelchair and power system should be tested to relevant RESNA standards and also evaluated clinically to determine potential benefits and limits of use.

## 2.6 Clinical Testing of Wheeled Mobility Devices

In addition to laboratory testing, CLOUT includes comprehensive clinical testing for wheeled mobility devices. A standardized approach for clinical testing, performed by multi-disciplinary subject matter experts, should be used to ensure that requirements for using the device are well understood, that all aspects of safety from a clinical perspective are evaluated, and that limits of use are clearly defined.

A common type of clinical testing by subject matter experts is activity analysis, which is a practice commonly used by rehabilitation therapists (e.g., occupational and physical therapists) as a framework for assessing an activity while it is being performed.[50,51] This framework was designed to consider the activity as it could be conducted by any person. This process

can be adapted for CLOUT so that it serves as a framework for clinical testing of various medical technologies, such as wheeled mobility devices. The framework has two components. First, device evaluation in a controlled laboratory space is conducted. This consists of evaluating requirements for device assembly and disassembly, installation or uninstallation of the device (if applicable), the interface of the device with the person using it (e.g., fit, comfort, seating and positioning support), the engagement or disengagement of the person with the device (e.g., transferring into and out of), the process of using of the device in an indoor controlled setting, and review of care, maintenance, and storage requirements.

Second, device evaluation in anticipated usage scenarios is performed. The wheeled mobility device is propelled, driven, or pushed in all indoor and outdoor environments that may be encountered through typical usage. Requirements for stowing the wheeled mobility device in a vehicle with or without assistance are considered and trialed, and options for transportation by personal vehicle and public transit are explored. A thorough activity analysis also includes evaluation of any materials that accompany the device (e.g., video instructions, user manuals, maintenance manuals). Video recording of the process of conducting the activity analysis is recommended for reference and recordkeeping.

In some cases, further evaluation of the physical performance of the device in various conditions or environments is needed as an adjunct to clinical and laboratory testing to established standards. It is important to note that standardized tests may not exist for the relevant situations in which the device should be evaluated for unique circumstances. Therefore, additional tests may need to be developed. Such engineering testing includes documentation of the condition under which the testing was performed and selection of relevant tests to be conducted.

For the purposes of establishing a CLOUT framework for evaluating wheeled mobility devices, two devices, the Action Trackchair and the Rio Mobility Firefly, were chosen as case examples for activity analysis by subject matter experts. The Action Trackchair was chosen to exemplify a unique mobility device beyond typical power wheelchair groups coded by CMS, and one that is intended to be used outdoors in extreme terrain. Tests did not exist for some relevant testing scenarios so they needed to be developed (e.g., drag test). The Firefly was chosen to exemplify a device that can be installed on a manual wheelchair frame, and could theoretically change the limits of use of the device to which it is being mounted. Example reports are provided (see Appendices) and can serve as a template for future evaluation of other devices.

Clinical testing, when combined with laboratory testing to established standards and innovative testing for unique circumstances, supports determination of limits of use when critical factors related to human body structures and functions, activities, and environment are considered. Determining clinical limits of use for any device requires a strong understanding of product features and common usage scenarios, regulation and coding, existing test standards, and performance expectations. Requirements for care, maintenance, storage and Veteran training must also be determined.

## 2.7 American National Standards for Wheelchairs

There are currently nineteen sections of the RESNA American National Standards for Wheelchairs that apply to manual and powered wheelchairs:[20]

**Section 1: Determination of static stability**

This section measures the angle or slope of the ground at which the wheelchair will tip over in the forward, backward and sideways directions in different setup configurations.

**Section 2: Determination of dynamic stability of electrically powered wheelchairs**

This section determines the how/if a powered wheelchair tips when it is traveling, stopping and starting on sloped surfaces.

**Section 3: Determination of effectiveness of brakes**

This section determines how a power wheelchair behaves when braking over different surfaces.

**Section 4: Energy consumption of electrically powered wheelchairs and scooters for determination of theoretical distance range**

This section determines how far a power wheelchair will travel if the battery is fully charged.

**Section 5: Determination of dimensions, mass and maneuvering space**

This section determines the general sizing of the wheelchair that is often reported in the user manual and is important to review when stakeholders choose a wheelchair.

**Section 6: Determination of maximum speed, acceleration and deceleration of electrically powered wheelchairs**

This section determines the driving behavior of a powered wheelchair that should be taken into account when selecting a wheelchair.

**Section 7: Method of measurement of seating and wheel dimensions**

Similar to Section 5, this section measures aspects of the seating system that are important to ensure the wheelchair user can be accommodated by the seating system.

**Section 8: Requirements and test methods for static, impact and fatigue strengths**

This section tests the reliability of the wheelchair under the expected loading that will occur during daily use.

**Section 9: Climatic tests for electrically powered wheelchairs**

This section determines whether a powered wheelchair behaves reliably after it is exposed to heat, cold, and rain conditions that would be expected during daily use or transport.

**Section 10: Determination of obstacle-climbing ability of electrically powered wheelchairs**

This section determines how high of an obstacle a powered wheelchair can climb.

**Section 11: Test dummies**

This section describes characteristics of the testing devices (i.e., dummies) that are used to represent the weight distribution of the human body during many of the tests described in other sections.

**Section 13: Determination of coefficient of friction of test surfaces**

This section describes how to measure the roughness of the test surfaces used during the tests described in other sections.

**Section 14: Power and control systems for electrically powered wheelchairs – Requirements and test methods**

This section provides information about the safety and performance of the wheelchair under circumstances where the electronics may be compromised, such as due to cut wires.

**Section 15: Requirements for information disclosure, documentation and labeling**

This section describes what information must be reported through stickers/tags on the wheelchair and in the user manual.

**Section 16: Resistance to ignition of upholstered parts – Requirements and test methods**

This section determines whether upholstered portions of the wheelchair are flame/burn resistant.

**Section 20: Determination of the performance of stand-up type wheelchairs**

This section is specific for stand-up wheelchairs, and describes how tests in other sections should be applied to these devices.

**Section 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and motorized scooters**

This section determines whether powered wheelchairs operate safely while they are exposed to electromagnetic disturbances that are common in the environment.

**Section 22: Set-up procedures**

This section describes how to setup the wheelchair for the tests described in the other sections.

**Section 26: Vocabulary**

This section provides definitions for the vocabulary used throughout the other sections.

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# 3 Applying CLOUT to Wheeled Mobility Devices



## 3.1 Purpose

This section describes the template used to capture the considerations for identifying limits of use and provides instructions for using visual materials (e.g., dashboards). As a result, this section can be used independently as a reference to sections 4 through 6.

## 3.2 Overview of CLOUT

In Sections 4 through 6, application of CLOUT for wheeled mobility devices is demonstrated through examples for manual wheelchairs, power wheelchairs, and power operated vehicles, known as scooters. Each of these respective sections is intended to serve as a stand-alone document that can be excerpted for future reference, which explains why some repeat information is included.

A standardized template is used consistently in each section to capture the considerations for determining the clinical limits of use for wheeled mobility devices. **Figure 2** below demonstrates the considerations that contribute to identifying the limits of use for a specific type or category of device. Once limits of use are identified, strategies for mitigation are proposed.

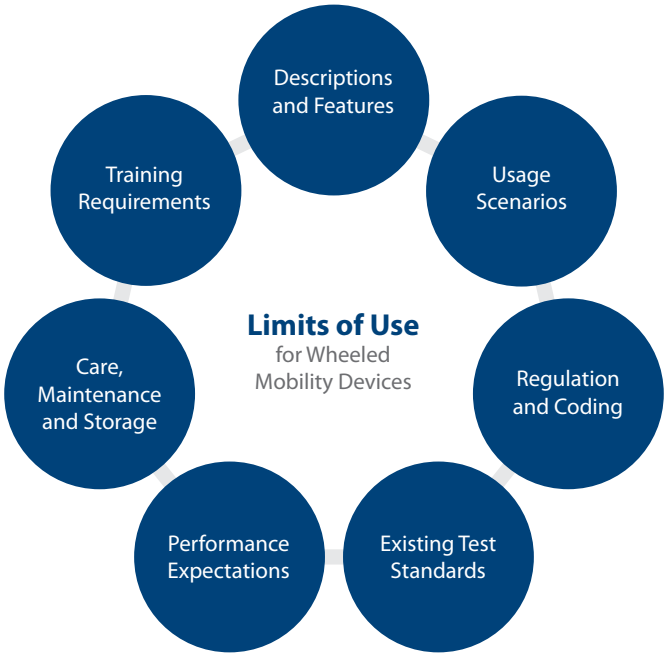


**Figure 2** Considerations for establishing limits of use for wheeled mobility devices

# 3.3 Visual Dashboards to Assist With Wheeled Mobility Device Comparison

## 3.3.1 How to Use Dashboards

Following each CLOUT example, a visual dashboard with color indicators summarizes the detailed narrative, and is intended to serve as a quick reference. The dashboards provide an overview of the device categories within both manual wheelchairs and power mobility devices. The dashboard colors demonstrate the extent to which device factors (e.g., seating system customizable), activity factors (e.g., part-time use), and environmental factors (e.g., outdoor mobility in the community) are representative of product categories. The dashboard is not exhaustive and does not include all possible or rare exceptions. Instead, the dashboard is intended to represent ideal or typical scenarios based on good clinical practice. Exceptions will always exist. It is also important to note that the devices available on the market change from time to time. The dashboard therefore is meant to represent the most common devices available at the time this document was written or updated.

The color coding is defined as:

- **Red** – common products in that category do not typically have that feature or are not typically clinically appropriate in that scenario.
- **Yellow** – a limited selection of products in that category typically have that feature, or common products in that category have limitations and may not always be clinically appropriate in that scenario.
- **Green** – most or all products in that category typically have that feature, or the most common products in that category are usually clinically appropriate in that scenario.

# 4 Manual Wheelchairs



## 4.1 Purpose

This section describes the features of manual wheelchairs and relevant regulation and coding; test standards; transportation safety issues; performance expectations; care, maintenance and storage requirements; and training considerations. As a result, this section can be used independently as a reference to understand the limits of use of manual wheelchairs.

## 4.2 Product Information

**Description and features:** Manuals wheelchairs are non-powered wheeled mobility devices with four wheels and an integrated seating system consisting of a seat surface and back support. Manual wheelchairs range from highly adjustable, highly customizable devices intended for independent propulsion and advanced mobility skills to non-adjustable, non-customizable devices that are not intended for self-propulsion. The key features by which manual wheelchairs vary are frame construction (folding vs. rigid), materials, device weight, and customizability by configuration, adjustments and available accessories. Some manual wheelchairs accommodate the option for a reclining back support; others are designed with tilt, partial seat elevation or standing options. Heavy duty versions of some models are available to accommodate Veteran weights greater than 250 pounds.

**Usage Scenarios Based on Personal, Activity and Environment Factors:** Manual wheelchairs are used by individuals who require mobility support due to impaired walking that is not resolved by an ambulation assistive device (e.g., cane, crutch, walker, or rollator). Usage scenarios are highly variable, ranging from individuals who require a wheelchair for part-time, intermittent use, those who are pushed in the wheelchair by another person and individuals who require a wheelchair as their full-time mobility device necessary for performing advanced skills in all environments. Some manual wheelchairs are indicated only for limited indoor and controlled outdoor environments, such as paved surfaces and American with Disabilities Act (ADA) compliant ramps. Highly specialized manual wheelchairs, when fit appropriately and adjusted properly, can be used to perform advanced mobility skills in the outdoor unbuilt environment, including extreme terrain.

**Regulation and Coding:** The US Food and Drug Administration (FDA) regulates manual wheelchairs as Class I medical devices. Requirements include company registration and device listing, and an approved 510k application for determination of substantial equivalency and clearance for marketing. HCPCS codes are assigned based on device weight, features, and occupant weight capacity (K0001-K0008, E1161 (tilt), E1225-26 (recline accessory), E1038-39 (transport)).

**Existing Test Standards:** As an FDA Class I medical device, objective laboratory testing of manual wheelchairs is not mandatory. The Centers for Medicare and Medicaid Services (CMS) does not require testing and does not code manual wheelchairs based upon performance requirements. Voluntary standards have been developed to evaluate wheelchair safety, performance and durability. In the U.S., the recognized consensus standards for manual wheelchairs are documented in Rehabilitation Engineering and Assistive Technology Society of North America (RESNA) Standard for Wheelchairs Volume 1 and Volume 2. Comparable international standards (ISO) are the ISO 7176 series. Products may be tested to RESNA and/or ISO standards; both are acceptable. Testing of manual wheelchairs has indicated large variability in results, especially related to durability. Standard (K0001) wheelchairs have failed faster than K0003-K0005 wheelchairs, with ultralight wheelchairs (K0005) having the highest durability and cost value. Purchasers and prescribers of manual wheelchairs should consider the life-cycle cost in addition to the purchase price for wheelchairs. There are differences in durability, strength and stability (tipping) amongst different types of wheelchairs. Test reports should be requested and reviewed, as the test results provide valuable information about manual wheelchair safety, performance and durability, provide objective information for wheelchair comparison, and can be useful when attempting to identify the most appropriate manual wheelchair for a Veteran.

**Transportation Safety:** A manual wheelchair that can be used safely as a seat in a motor vehicle (i.e., one that has been crash tested) is indicated for those who cannot transfer to a vehicle seat, or choose not to due to medical reasons or safety concerns. A mobility device that will be used as a seat in a vehicle should be tested to and comply with RESNA WC-19, "Wheelchairs used as seats in motor vehicles." After-market seating system components (e.g., back supports) should comply with RESNA WC-20, "Wheelchair seating systems for use in motor vehicles." Only pediatric wheelchairs are required to be crash tested by CMS. Other wheelchairs may have been voluntarily crash tested by the manufacturer. Test reports should be requested to confirm that a wheelchair has been tested to and complies with WC-19 and/or WC-20. If compliance with transportation safety standards cannot be confirmed for a given product, the wheelchair should not be used as a seat in a motor vehicle. It is also important to confirm that the wheelchair tiedown and occupant restraint system (WTORS) utilized for wheelchair transportation has been tested to and complies with requirements outlined in RESNA WC-18, "Wheelchair tiedowns and occupant restraint systems for use in motor vehicles."

## 4.3 Performance Expectations

Features for HCPCS coding for adult manual wheelchairs are outlined in **Table 2** below. Excerpted from Local Coverage Article: Manual Wheelchair Bases – Policy Article (A52497). Adult manual wheelchairs have a seat width and depth of 15 inches or greater. Minimum requirements are presented in **Table 2**.

**Table 2** Manual Wheelchair Features and Codes

| Feature | K0001 | K0002 | K0003 | K0004 | K0005 | K0006 | K0007 | E1161 | E1038[a] E1039[b] |
|---|---|---|---|---|---|---|---|---|---|
| Total Mass Without Front Riggings (Pounds) | >36 | >36 | 34-36 | <34 | <30 | NS ① | NS ① | NS ① | NS ① |
| Seat to Floor Height (Inches) | >19 | <19 | NS ① | NS ① | NS ① | NS ① | NS ① | NS ① | NS ① |
| Weight Capacity (Pounds) | <250 | <250 | 250 | NS ① | NS ① | >250 | >300 | NS | < 300[a] > 300[b] |
| Large Wheels for Self-Propulsion | YES | YES | YES | YES | YES | YES | YES | NO | NO |
| Adjustable Rear Axle Position | NO | NO | NO | YES ② | YES | NO | NO | NO | NO |
| Lifetime Warranty Side Frame and Cross Braces | NO | NO | NO | YES | YES | NO | NO | YES | YES |

① **NS** = Not Specified

② * = Minimally Adjustable

Specific features required for HCPCS coding are not clearly identified for K0008 "Custom Manual wheelchair/base" and K0009 "Other manual wheelchair/base." Therefore, the details about these two codes are not captured in the summary table.

Additional performance measures that provide critical information to determine product quality and usability include the following:

Objective test results from standards:

- Static stability of the wheelchair is measured using methods described in Section 1 of RESNA, and reveals the angles that the wheelchair tips over in the forward, rearward and lateral directions when the wheelchair is setup in both the most and least stable configuration.
- Static, Impact and Fatigue Strength are measured using methods described in Section 8 of RESNA and whether the wheelchair can endure routine forces without failing. This test is a critical measure that includes pass/fail criterion that are often used by regulators to determine if the product should be provided. While CMS does not currently require manual wheelchairs to pass durability tests, minimum performance

criteria are established that the expected lifetime of the device is at least three years, and compliance should be required by all funding sources. Based on RESNA standards, meeting this 3-year lifetime performance requirement is based on performance on the durability tests, which include:

  - Completing 200,000 cycles of a Fatigue test on a level surface with slats
  - Completing 6,666 cycles of a Curb-Drop test
- Effectiveness of Brakes are tested using methods described in Section 3 of RESNA and provide information about the stopping power and stability of the wheelchair when the brakes are engaged.

Clinical performance testing can provide critical qualitative information on the following factors:

- Responsiveness indicates the behavior of the wheelchair when the Veteran or an attendant attempt to move the device.
- Fabrication quality provides insight into the quality of construction, assembly, and materials utilization and management.
- Ergonomic design for body support and transfers in and out of the device indicates how the device can be used safely and effectively by different Veterans.
- Usability for device operation, adjustments, and maintenance of all features determines necessary Veteran abilities and device limitations.

**Note:** Several different types of accessories are available that add a power supply to a manual wheelchair. Power add-on options convert a manual wheelchair to a joystick controlled (E0983) or tiller controlled (E0984) power mobility device. Pushrim activated power assist wheels (E0986) provide power augmentation when a propulsive force is applied or power is activated by contact with the pushrim. When any power system is added to a manual wheelchair, the manual wheelchair is altered. Objective lab testing to RESNA standards and thorough clinical evaluation provide critical information about device features (including impact to and interface with the manual wheelchair), performance, limitations, and safety considerations. Several RESNA standards for power wheelchairs apply when power is added to a manual wheelchair. FDA regulates power add on systems as Class II medical devices.

**Care, Maintenance & Storage Requirements:** Manual wheelchairs must be properly maintained to support optimal performance. All components must be kept clean and dry. When not in use, they must be stored in a clean, dry indoor location. Tires must be properly inflated. The User Manual or Instructions for Use should clearly describe care, maintenance and storage recommendations in addition to instructions for operation, adjustments and installation of accessories.

**Veteran Training Requirements:** The Veteran who is provided a manual wheelchair must receive education and training for propelling or being pushed on appropriate surfaces and between obstacles. Those who self-propel must learn to move the wheelchair forward and backwards, maneuver the wheelchair for turns and navigation in limited spaces, safe and effective management of wheel locks, and management of moving accessories such as leg rests, arm supports and anti-tip devices. Veterans who will use the manual wheelchair full time or for an extended time frame (beyond three months) should be provided with advanced skills training, including performance of "wheelies" to support safe and independent mobility in varied circumstances and environments. Veteran training is required for transferring in and out of the manual wheelchair from varied surface heights, including management of moving components. Training for appropriate stowage in a vehicle, including disassembly and reassembly, is also indicated along with review of general care, maintenance and storage recommendations.

# 4.4 Limits of Use

Manual wheelchairs are not intended for Veterans whose comprehensive mobility needs can be adequately addressed through use of an ambulation assistive device (cane, crutch, walker, or rollator). Manual wheelchairs intended for self-propulsion are not indicated for individuals who are not capable of effective self-propulsion at acceptable velocities or who cannot perform adequate pressure management without alternative positioning (e.g., tilt or recline) or power seat functions. They are typically not appropriate for those who cannot transfer independently. Manual wheelchairs that are not intended for self-propulsion are not indicated for individuals who either 1) have sufficient upper limb function and other physical and cognitive abilities to propel and manage a manual wheelchair; or 2) are better served with a power wheelchair with power seat functions. While exceptions exist, a manual wheelchair does not usually work well for an individual who requires a ventilator. Unless the manual wheelchair complies with WC-19 and WC-20, it is not appropriate for Veterans who must be transported seated in the wheelchair while in a vehicle. Objective device testing indicates that some manual wheelchairs are limited in durability, stability and strength.

## 4.4.1 Limits of Use by Manual Wheelchair Categories

**Transport wheelchairs** (E1038/39): Transport wheelchairs are folding or rigid frame mobility devices that are pushed by an attendant. They are indicated for individuals who cannot effectively self-propel a manual wheelchair or use a power mobility device. The rear wheels are similar in size to the front casters, are not designed for self-propulsion, and position cannot be adjusted. A limited number of accessories are available such as oxygen tank holders and elevating leg supports. A transport manual wheelchair is appropriate to be used on firm, level, indoor and outdoor surfaces. Most transport wheelchairs accommodate Veteran weights of 300 pounds or above.

There are many limits of use of transport wheelchairs. Transport wheelchairs are not appropriate for individuals with a full time or permanent need for wheeled mobility support, or who are capable of self-propelling a manual wheelchair or driving a power mobility device. Transport wheelchairs are not intended for use on uneven terrain, sloped surfaces or carpet. Since adjustments, accessories and customization are extremely limited, the transport wheelchair does not provide optimized comfort, soft tissue protection, postural support or joint preservation. Some transport manual wheelchairs fold for stowing, but rigid frames do not. The ability to disassemble into component parts is limited. They cannot be occupied safely as a seat in a moving vehicle. Not all models accommodate Veteran weights above 300 pounds.

**Standard manual wheelchairs** (K0001, K0002, K0003, K0006, K0007 – codes are grouped together for similar features with differences identified by codes as captured in **Table 2**): Standard manual wheelchairs are folding, minimally adjustable, manually propelled or attendant managed wheelchairs. Most features are fixed; leg rest length and arm support height are potentially adjustable. The rear wheel is positioned at the rearward aspect of the frame and wheel position is not adjustable. Front casters and rear wheels usually have solid tires; pneumatic rear tires are sometimes an option. Limited selections of accessories are available such as elevating leg rests, wheel lock extensions, anti-tip devices, cane/crutch supports, and

oxygen tank holders. Standard manual wheelchairs are appropriate to be used on firm, level, indoor and outdoor surfaces.

There are several limits of use of standard manual wheelchairs. They are not appropriate for individuals with a full time or permanent need for wheeled mobility support. They are not intended for use on uneven terrain, sloped surfaces or carpet. Since adjustments, accessories and customization are extremely limited, standard manual wheelchairs do not provide optimized comfort, skin protection, postural support or joint preservation. Foot propulsion is not recommended except when a lower seat to floor height is available (e.g., K0002) to allow reasonable positioning in space for adequate foot contact with the floor. These wheelchairs do not support standing or an elevated seated position. They fold for stowing but are not easy to disassemble into component parts. They cannot be occupied safely as a seat in a motor vehicle. Only some standard wheelchairs (K0006/K0007) accommodate Veteran weights above 250 pounds. Just one type of standard wheelchair requires a seat to floor height less than 19 inches (K0002). Just one type of standard wheelchair weighs less than 36 pounds (K0003).

**Manual Recline** (E1225/E1226): Manual wheelchairs that accommodate a manual recline mechanism are similar to standard manual wheelchairs but provide the option for an alternative position in space. The back support, with a head support extension, can be manually moved or positioned in a reclined position ranging from near vertical to near horizontal. Manual elevating leg rests are usually included. These wheelchairs are typically indicated for individuals with short term mobility impairment that either have hip flexion range of motion (ROM) restrictions or ROM limitations or require a reclined position to support physiologic needs.

There are several limits of use in addition to those identified for standard manual wheelchairs. Manual wheelchairs with recline are heavy due to additional hardware, increased back height and head support extension, and elevating leg rests. They are therefore more difficult to self-propel and more difficult for an attendant to push. They are also more challenging to disassemble for stowage in vehicles and require additional space for maneuvering, stowage in a vehicle, and storage when not occupied. These manual wheelchairs fold for stowing but are not easy to disassemble into component parts. They cannot be occupied safely as a seat in a motor vehicle. Most manual wheelchairs with recline do not accommodate Veteran weights above 250 pounds.

**Manual Tilt in Space** (E1161): Manual wheelchairs with a manual tilt mechanism are similar to transport wheelchairs but provide the option for an alternative position in space. The seat and back support, with a head support extension, can be manually moved or positioned in a tilted position. These wheelchairs are typically indicated for individuals with long term mobility impairment that cannot self-propel a manual wheelchair and require repositioning for pressure management, postural support or management of physiologic needs. They are designed to accommodate some additional components and products that provide seating and positioning support and have some selections for options and accessories to customize the device for the individual. Devices are available that accommodate Veteran weights above 300 pounds.

There are several limits of use in addition to those identified for transport manual wheelchairs. Manual wheelchairs with tilt are heavy due to additional hardware, increased back height and head support extension. They are challenging to stow in vehicles and require additional space for maneuvering, stowage in a vehicle, and storage when not occupied. They cannot be occupied safely as a seat in a motor vehicle.

**High strength lightweight** (K0004): Manual wheelchairs classified as high strength, lightweight are similar in design to standard manual wheelchairs. However, materials and construction support increased durability, they are lighter in overall weight (less than 34 pounds) and the rear wheel position on some wheelchairs is partially adjustable, which supports increased propulsion efficiency. They are typically appropriate for part-time or intermittent use. Some configuration and customization options are available. These wheelchairs are appropriate to be used on firm, level, and indoor surfaces and outdoors on ADA compliant ramps and surfaces when adequate education and training has been provided. They can be dissembled for stowing, typically with the help of a caregiver.

There are several limits of use of high strength lightweight wheelchairs. They are not appropriate for individuals with a full time or permanent need for wheeled mobility support. They are not intended for advanced mobility skills or use on uneven or extreme terrain or inclement weather. They cannot be occupied safely as a seat in a moving vehicle unless they have been tested to WC-19 and WC-20. They do not accommodate Veteran weights above 250 pounds.

**Ultralight folding and rigid** (K0005): Ultralight folding and rigid manual wheelchairs are the most appropriate manual wheelchairs for full time, permanent use. They can be customized for the individual by configuration and/or adjustment. A wide range of accessories are available to support unique needs. The rear wheel position is highly adjustable and can be configured for optimal propulsion and advanced wheelchairs skills. Individuals who have received appropriate education and training can use ultralight wheelchairs in outdoor uneven and sometimes extreme terrain. Both folding and rigid models can be stowed in a vehicle either independently or with assistance of a caregiver. Ease of stowing is supported by efficient removal of the rear wheels. Some models have been tested to WC-19 and WC-20 and can be used safely as a seat in a motor vehicle. There is at least one model that supports partial seat elevation.

Ultralight manual wheelchairs have some limits of use. They do not provide optimal mobility for individuals who are better served with a power wheelchair based on comprehensive needs. Folding ultralight wheelchairs are somewhat challenging to stow either independently or with assistance of a caregiver because the back support does not fold down. Only some models can be used safely as a seat in a motor vehicle. Only some models accommodate Veteran weights above 250 pounds.

### 4.4.2 Limits of Use Mitigation

Limits of use of manual wheelchairs are mitigated by providing a more appropriate manual wheelchair that can be adjusted or configured for the Veteran or by providing a power mobility device that can be programmed, configured and adjusted to meet Veteran needs. Comprehensive Veteran education and training may partially mitigate limits of use.

# 4.5 Manual Wheelchair CLOUT Visual Dashboard

| Category | | Ultralight Rigid & Folding | High Strength Lightweight | Lightweight | Standard | Standard Hemi | Standard Heavy Duty | Tilt-In-Space | Recline | Transport |
|---|---|---|---|---|---|---|---|---|---|---|
| **CMS K Codes** | | K0005 | K0004 | K0003 | K0001 | K0002 | K0006<br>K0007 | E1161 | E1225<br>E1226* | E1038<br>E1039 |
| **Wheelchair Weight (Lb.)** | | < 30 | < 34 | 34-36 | > 36 | > 36 | NS ① | NS ① | NS ① | NS ① |
| **Seat Height (Inches)** | | NS ① | NS ① | NS ① | > 19 | < 19 | NS ① | NS ① | NS ① | NS ① |
| **Device Features** | Backrest Angle (C) ② | | | | | | | | | |
| | Seat Plane Angle (C) ② | | | | | | | | | |
| | Accommodate Seating/Positioning Items | | | | | | | | | |
| | Rear Wheel Position (C) ② | | | | | | | | | |
| | Front Rigging Position (C) ② | | | | | | | | | |
| | Seat To Floor Height (C) ② | | | | | | | | | |
| | Options & Accessories to Customize | | | | | | | | | |
| | Supports Tilt In Space | | | | | | | | | |
| | Supports Standing | | | | | | | | | |
| | Supports Seat Elevation | | | | | | | | | |
| | Standard Duty (≤ 250 Lb) | | | | | | | | | |
| | Heavy Duty (251-300 Lb) | | | | | | | | | |
| | Extra Heavy Duty (≥ 301 Lb) | | | | | | K0007 | | | E1039 |
| **Activity** | Part-Time Or Temporary Use | | | | | | | | | |
| | Full-Time Or Permanent Use | | | | | | | | | |
| | Dependent Propulsion | | | | | | | | | |
| | Independent Propulsion On Varied Terrain | | | | | | | | | |
| | Supports Advanced Mobility Skills | | | | | | | | | |
| | Safe As Seat During Transportation | ③ | ③ | | | | ③ | ③ | | ③ |
| | Transportable in Dependent Manner | | | | | | | | | |
| | Transportable in Independent Manner | | | | | | | | | |
| **Environmental** | Indoor Mobilityiln The Home | | | | | | | | | |
| | Indoor Mobility in The Community | | | | | | | | | |
| | Outdoor Mobility in Built Environment | | | | | | | | | |
| | Outdoor Mobility in Unbuilt Environment | | | | | | | | | |
| | Outdoor Mobility in Inclement Weather | | | | | | | | | |
| | Outdoor Mobility in Extreme Terrain | | | | | | | | | |

① NS = Not Specified

② C = Customizable by Adjustability and/or Configurability

③ * = Only WC-19/WC-20 Compliant Wheelchairs

- **Red** – common products in that category do not typically have that feature or are not typically clinically appropriate in that scenario.
- **Yellow** – a limited selection of products in that category typically have that feature, or common products in that category have limitations and may not always be clinically appropriate in that scenario.
- **Green** – most or all products in that category typically have that feature, or the most common products in that category are usually clinically appropriate in that scenario.

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# 5 Power Wheelchairs



## 5.1 Purpose

This section describes the features of power wheelchairs and relevant regulation and coding; test standards; transportation safety issues; performance expectations; care, maintenance and storage requirements; and training considerations. As a result, this section can be used independently as a reference to understand the limits of use of power wheelchairs.

## 5.2 Product Information

**Description and Features:** Electric power wheelchairs (hereafter referred to as "power wheelchairs") are battery power mobility devices with two main drive wheels and two or four casters. Front and rear wheel drive power wheelchairs have two casters, while mid-wheel drive power wheelchairs have four casters. Depending on the make and model, power wheelchairs have either an integrated seating system with a captain style seat, or a fully customizable seating system in which various cushions, backrests and supports can be added. Power wheelchairs are typically operated with a joystick, but some can be operated with an alternative control such as a "sip and puff," or head array. Standard power wheelchairs cannot accommodate power seat functions, but some advanced power wheelchairs can accommodate power tilt, recline, seat elevation, standing and/or elevating leg rests. Some advanced power wheelchairs also have features that support operation of computers, tablets, smart phones, augmentative communication systems, and the home environment. Heavy duty versions of some models are available to accommodate higher Veteran weights.

**Usage Scenarios Based on Personal, Activity & Environment Factors:** Power wheelchairs are in some cases used by individuals who require part-time or intermittent mobility support due to impaired walking that is not resolved by an ambulation assistive device (e.g., cane, crutch, walker, or rollator), manual wheelchair, or a scooter. In other cases, power wheelchairs are used by individuals who do not walk, may or may not be able to transfer in and out of the device on their own and may require postural support and/or power seat functions for soft tissue protection or other functional or physiological purposes. Depending on the specific model, power wheelchairs perform differently indoors and outdoors and across various types of surface because device characteristics vary widely. Basic power wheelchairs can be safely used only on flat, indoor environments. Other power wheelchairs can be used both indoors and outdoors, including paved surfaces and American with Disabilities Act (ADA) compliant ramps. The most advanced power wheelchairs have additional features that allow for more robust maneuverability in outdoor environments including uneven terrain.

**Regulation and Coding:** The US Food and Drug Administration (FDA) regulates power wheelchairs as Class II medical devices. Requirements include company registration and device listing, and an approved 510K application for determination of substantial equivalency and clearance for marketing. CMS HCPCS codes are assigned to Group 1 (K0813 – K0816), Group 2 (K0820 – K0843), Group 3 (K0848 – K0864), Group 4 (K0868 – K0886) and Group 5 pediatric (K0890-K0891) power wheelchairs, based on tested and reported performance and occupant weight capacity. It is important to note that although multiple codes exist in each group, commercial products may not exist for every code.

**Existing Test Standards:** As an FDA Class 2 medical device, power wheelchairs must be adequately tested to demonstrate product safety, performance and durability. In the U.S., the recognized consensus standards for power wheelchairs are documented in the Rehabilitation Engineering and Assistive Technology Society of North America (RESNA) Standard for Wheelchairs Volume 1 and Volume 2. Comparable international standards (ISO) are the ISO 7176 series. Products may be tested to RESNA and/or ISO standards; both are acceptable. CMS requires power wheelchairs to meet or exceed specific performance and durability criteria when tested to the RESNA standards. Power wheelchair categories defined by CMS have different criteria that a device must meet to be coded in a specific category (**Table 3**). Testing of power wheelchairs has indicated large variability in results, especially related to stability (tipping), strength, durability, environmental tolerance, and power and control system failures.[35,42,43,45] Test reports should be requested and reviewed, as the test results provide valuable information about power wheelchair safety, performance and durability, provide objective information for power wheelchair comparison, and can be useful when attempting to identify the most appropriate power wheelchair for a Veteran.

**Transportation Safety:** Individuals who cannot transfer to a vehicle seat, or choose not to due to medical reasons or safety concerns must be provided a wheelchair that can be used safely as a seat in a motor vehicle, which means that it complies with RESNA WC-19. After-market seating systems (such as add-on back supports) should comply with RESNA WC-20, "Wheelchair seating systems for use in motor vehicles." Only pediatric power wheelchairs are required to be crash tested by CMS. Other wheelchairs may have been voluntarily crash tested by the manufacturer. Test reports should be requested to confirm that a wheelchair has been tested to and complies with WC-19 and/or WC-20. If compliance with transportation safety standards cannot be confirmed for a given product, the wheelchair should not be used as a seat in a motor vehicle. It is also important to confirm that the wheelchair tiedown and occupant restraint system (WTORS) utilized for wheelchair transportation has been tested to and complies with requirements outlined in RESNA WC-18, "Wheelchair tiedown and occupant restraint systems for use in motor vehicles."

## 5.3 Performance Expectations

Minimum performance measures for HCPCS coding are outlined in **Table 3** below. *Excerpted from Local Coverage Article: Power Mobility Devices – Policy Article (A52498).*

**Table 3** Minimum Performance Measures for HCPCS Coding

| Test Results | Group 1 | Group 2 | Group 3 | Group 4 |
|---|---|---|---|---|
| Maximum Length (In) | 40 | 48 | 48 | 48 |
| Maximum Width (In) | 24 | 34 | 34 | 34 |
| Obstacle Height (Mm) | 20 | 40 | 60 | 75 |
| Minimum Top Speed (Mph) | 3 | 3 | 4.5 | 6 |
| Minimum Range (Miles) | 5 | 7 | 12 | 16 |
| Dynamic Stability Incline (Degrees) | 6 | 6 | 7.5 | 9 |
| Drive Wheel Suspension | No | No | Yes | Yes |
| Fatigue Test on Level with Slats (Cycles) | 200,000 | 200,000 | 200,000 | 200,000 |
| Drop Test (Cycles) | 6,666 | 6,666 | 6,666 | 6,666 |

Additional performance measures provide critical information to determine product quality and usability including the following:

Objective test results from standards:

- Pivot width (turning radius) indicates the space required to turn the device around. This is related to drive wheel position and length of the wheelchair.
- Total device mass determines vehicle and air transportation options and compatibility with indoor environments, especially the load capacity of the floor.
- Mass of heaviest part must be known to determine physical and functional requirements for assembly, disassembly and stowage for transportation.

Clinical performance testing provides critical qualitative information on the following factors:

- Responsiveness indicates the behavior of the wheelchair when the Veteran activates the drive control.
- Fabrication quality provides insight into the quality of construction, assembly, and materials utilization and management.
- Ergonomic design for body support and transfers in and out of the device indicates how the device can be used safely and effectively by different Veterans.
- Usability for device operation, adjustments, and maintenance of all features determines necessary Veteran abilities and device limitations.

**Note:** Some power wheeled mobility devices have enhanced features and/or unique capabilities that do not fit in Groups 1-4 for performance requirements and respective HCPCS code descriptors. Objective lab testing to RESNA standards and thorough clinical evaluation provide critical information about device features, performance, limitations and safety considerations. If the device is a power wheelchair, FDA regulation as a Class II medical device applies.

**Care, Maintenance & Storage Requirements:** The power wheelchair must be properly maintained to support optimal performance. All components must be kept clean and dry. When not in use, the power wheelchair should be stored in a clean, dry indoor location. Electrical outlet access is needed for battery charging. The User Manual or Instructions for Use should clearly describe care, maintenance and storage recommendations in addition to instructions for general assembly and installation of accessories, adjustments, and device operation.

**Veteran Training Requirements:** The Veteran who is provided a power wheelchair must receive education and training for driving on appropriate surfaces and between obstacles. Veteran training is required for efficient and safe transferring in and out of the power wheelchair and for managing moving components. Training for appropriate stowage and securement for transport in a vehicle, including disassembly and reassembly (where applicable), is also indicated along with review of general care, maintenance and storage recommendations.

## 5.4 Limits of Use

Power wheelchairs are not intended for Veterans who have sufficient upper limb function and cardiorespiratory endurance to propel and manage a manual wheelchair or whose mobility needs can be adequately addressed through use of an ambulation assistive device or a scooter. Independent lab testing indicates that some power wheelchairs are limited in durability, stability, effectiveness of brakes, and power and control system safety, and are most likely to fail during strength and climatic testing. Performance characteristics for minimum top speed, minimum range, obstacle height and dynamic stability on an incline help to determine which environments may be limiting to the use of a power wheelchair.

### 5.4.1 Performance & Limits of Use by Power Wheelchair Group

**Group 1:** Performance characteristics indicate that the Group 1 power wheelchairs are most appropriate for flat, indoor home use for limited distances. While maximum overall dimensions are 40 x 24 inches, some models are modular which allows for disassembly for stowage and transportation.

There are several limits of use of Group 1 power wheelchairs. The lack of an expandable controller and no ability to add alternative controls limits Veterans to a joystick to operate the power wheelchair. Inability to add any seat functions restricts appropriate use to individuals who can ambulate to some degree, transfer in and out of the device, and pressure relieve independently. It also limits the use to those who do not need seat functions for standing or physiological purposes. Group 1 power wheelchairs cannot be used by those who need a ventilator. Group 1 power wheelchairs are limited to being used on a temporary or intermittent basis on flat, indoor surfaces. They cannot be used as a seat in a motor vehicle. Only some models can be safely secured unoccupied in a vehicle. Group 1 power wheelchairs do not accommodate Veteran weights above 300 pounds.

**Group 2:** Performance characteristics indicate that the Group 2 power wheelchairs are most appropriate for indoor home or community environments for limited distances. While maximum overall dimensions are 48 x 34 inches, some models are modular which allows for disassembly for stowage and transportation.

There are several limits of use of Group 2 power wheelchairs that do not have power options (K0820-K0829). These power wheelchairs lack an expandable controller and have no ability to add alternative controls, which limits Veterans to a joystick to operate the wheelchair. Lack of ability to add any seat functions restricts use to individuals who can ambulate to some degree, can transfer in and out of the device, and pressure relieve independently. It also limits the use to those who do not need seat functions for standing or physiological purposes. These power wheelchairs cannot be used by those who need a ventilator. These Group 2 power wheelchairs have some limitations of use in outdoor environments and are not ideal for full-time users who need to traverse varying indoor and outdoor environments or inclement weather. Only some models can be used as a seat in a motor vehicle. Only some models can be safely secured unoccupied in a vehicle. Only some models disassemble for stowing.

There are several limits of use of Group 2 power wheelchairs that do have power options (K0830/31, K0835-K0843). Only some models have an expandable controller (K0835-K0843); otherwise they have no ability to add alternative controls, which limits Veterans to a joystick to operate the power wheelchair. Lack of ability to include more than one seat function on most models limits the use to those who need only one power seat function for pressure relief or physiological purposes.

Although standing can theoretically be added to some Group 2 power wheelchairs, current commercially available Group 2 wheelchairs do not have this feature. Only some models can be used by those who need a ventilator. These Group 2 power wheelchairs have some limitations of use in outdoor environments and are not ideal for all-day users who need to traverse varying indoor and outdoor environments or inclement weather. Only some models can be used as a seat in a motor vehicle. Only some models can be safely secured unoccupied in a vehicle. No models disassemble for stowing. Group 2 wheelchairs do not accommodate Veteran weights above 450 pounds.

**Group 3:** Performance characteristics indicate that the Group 3 power wheelchairs are most appropriate for all day use in both indoor and outdoor built and unbuilt environments. Maximum overall dimensions are 48 x 34 inches, and these wheelchairs cannot be disassembled for stowage or transportation.

There are several limits of use of Group 3 power wheelchairs. Lack of ability to add more than one seat function on a limited number of models limits the use to those who need only one power seat function for pressure relief or physiological purposes. Although standing can theoretically be added to some Group 3 power wheelchairs, current commercially available Group 3 wheelchairs do not have this feature. Only some models can be used by those who need a ventilator. Group 3 power wheelchairs cannot be used to traverse extreme terrain or during inclement weather. Only some models can be used as a seat in a motor vehicle. Only some models can be safely secured unoccupied in a vehicle.

**Group 4:** Performance characteristics indicate that the Group 4 power wheelchairs are most appropriate for all day use in both indoor and outdoor built and unbuilt environments, and in inclement weather. Maximum overall dimensions are 48 x 34 inches, and these wheelchairs cannot be disassembled for stowage or transportation.

There are several limits of use of Group 4 power wheelchairs. Lack of ability to add more than one seat function on some models limits the use to those who need only one power seat function for pressure relief or physiological purposes. Only some models can be used by those who need a ventilator. Group 4 power wheelchairs have some limits of use in extreme terrain. Only some models can be used as a seat in a motor vehicle. Only some models can be safely secured unoccupied in a vehicle. Group 4 power wheelchairs do not accommodate Veteran weights above 600 pounds.

### 5.4.2 Limits of Use Mitigation

Limits of use of power wheelchairs are mitigated by providing a more sophisticated (higher group) power wheelchair, except in cases of some Group 4 power wheelchair models, which may be limited in options for increased weight capacities. Limits of use can also be mitigated by choosing models that can be configured and adjusted to meet comprehensive Veteran needs or that accommodate the specific features that the Veteran requires. Providing comprehensive Veteran education and training may partially mitigate limits of use.

# 5.5 Power Wheelchair CLOUT Visual Dashboard

| Outdoor Mobility | | Extensive | Moderate | Limited | | Very Limited |
|---|---|---|---|---|---|---|
| CMS Group | | PWC Group 4 | PWC Group 3 | PWC Group 2 | | PWC Group 1 |
| CMS K Codes | | K0868 – K0886 | K0848 – K0864 | K0830/31, K0835-K0843 (Power Option) | K0820-K0829 (No Power Option) | K0813 – K0816 |
| Minimum Top Speed (MPH) | | 6 | 4.5 | 3 | 3 | 3 |
| Minimum Range (Miles) | | 16 | 12 | 7 | 7 | 5 |
| Obstacle Height (MM) | | 75 | 60 | 40 | 40 | 20 |
| Drive Wheel Suspension | | YES | YES | NO | NO | NO |
| Dynamic Stability Incline (Degrees) | | 9 (1:8) | 7.5 (1:10) | 6 (1:12) | 6 (1:12) | 6 (1:12) |
| Device Features | Expandable Controller/Alternative Controls | | | Only K0835-K0843 | | |
| | Multiple Power Option | Only K0884-K0886 | Only K0861-K0864 | Only K0841-K0843 | | |
| | Single Power Option | Only K0872- K0886 | Only K0856- K0864 | | | |
| | Power Seat Elevation | | | Only K0830-K0831 | | |
| | Power Standing Option | | | | | |
| | Intended to Accommodate Seating/Positioning Items | | | | | |
| | Backrest Angle Customizable | | | | | |
| | Supports Tilt In Space | | | | | |
| | Accommodates Ventilator | Only K0884-K0886 | Only K0861-K0864 | Only K0841-K0843 | | |
| | Interfaces With Other Technologies (e.g., Smartphone, Communication Device, Computer, Environmental Control) | | | | | |
| | Standard Duty (≤ 300 Lb) | | | | | |
| | Heavy Duty (301-450 Lb) | | | | | |
| | Very Heavy Duty (451-600 Lb) | | | | | |
| | Extra Heavy Duty (≥ 601 Lb) | | | | | |
| Activity | Intended for Full Time Use for Primary Mobility | | | | | |
| | Supports Independent Driving in Varied Environments | | | | | |
| | Safe as Seat During Transportation | ① | ① | ① | ① | |
| | Can be Secured Unoccupied Inside a Vehicle | | | | | |
| | Disassembles for Stowing (Portable Available) | | | | Only K0820-K0821 | Only K0813-K0814 |
| Environmental | Indoor Mobility in the Home | | | | | |
| | Indoor Mobility in the Community | | | | | |
| | Outdoor Mobility in Built Environment | | | | | |
| | Outdoor Mobility in Unbuilt Environment | | | | | |
| | Outdoor Mobility in Inclement Weather | | | | | |
| | Outdoor Mobility in Extreme Terrain | | | | | |

① * = Only WC-19/WC-20 Compliant Wheelchairs

- **Red** – common products in that category do not typically have that feature or are not typically clinically appropriate in that scenario.
- **Yellow** – a limited selection of products in that category typically have that feature, or common products in that category have limitations and may not always be clinically appropriate in that scenario.
- **Green** – most or all products in that category typically have that feature, or the most common products in that category are usually clinically appropriate in that scenario.

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# 6 Power Operated Vehicles



## 6.1 Purpose

This section describes the features of power operated vehicles and relevant regulation and coding; test standards; transportation safety issues; performance expectations; care, maintenance and storage requirements; and training considerations. As a result, this section can be used independently as a reference to understand the limits of use of power operated vehicles.

## 6.2 Product Information

**Description and features:** Power Operated Vehicles (hereafter referred to as "scooters") are a battery powered mobility devices with three or four wheels, an integrated seating system with a standard or captain style seat, and a tiller for direct steering. Speed is adjusted through manually operated controls located on the tiller. Available adjustments are minimal. The seat may be height adjustable and can be unlocked to rotate to both the right and left. Power seat elevation is available on some models; other power seat functions such as tilt, recline, standing and elevating leg rests are not available.

**Usage Scenarios Based on Personal, Activity & Environment Factors:** Scooters are used by individuals who require part-time or intermittent mobility support due to impaired walking that is not resolved by an ambulation assistive device (e.g., cane, crutch, walker, rollator) or manual wheelchair. Appropriate scooter candidates have the ability to stand, take steps, and transfer in and out of the device without assistance, do not require postural support and/or soft tissue protection, and do not require a power wheelchair. In some cases, power seat elevation is used to support improved sit-to-stand or stand-to-sit transfers and improved reach from the seated position. A scooter is typically indicated for limited indoor and controlled outdoor environments, such as paved surfaces and American with Disabilities Act (ADA) compliant ramps. Highly specialized scooters designed to move at increased speeds and to navigate extreme terrain perform and function similar to an all-terrain vehicle, and are not typically considered medically necessary.

**Regulation and Coding:** The US Food and Drug Administration (FDA) regulates scooters as Class II medical devices. Requirements include company registration and device listing, and an approved 510K application for determination of substantial equivalency and clearance for marketing. The Centers for Medicare and Medicaid Services (CMS) HCPCS codes are assigned to Group 1 (K0800-K0802) or Group 2 (K0806-K0808) based on tested and reported performance and occupant weight capacity. It is important to note that although multiple codes exist in each group, commercial products may not exist for every code.

**Existing Test Standards:** In the U.S., the recognized consensus standards for scooters are documented in Rehabilitation Engineering and Assistive Technology Society of North America (RESNA) Standard for Wheelchairs Volume 1 and Volume 2. Comparable international standards (ISO) are the ISO 7176 series. Products may be tested to RESNA and/or ISO standards; both are acceptable. CMS requires scooters to meet or exceed specific performance and durability criteria when tested to the RESNA standards. The two scooter categories defined by CMS have different criteria that a device must meet to be coded in a specific category (**Table 4**). Testing of scooters has indicated large variability in results, especially related to stability (tipping), durability, environmental tolerance, and power and control system failures.[44] Scooters with bigger wheel bases and overall larger dimensions are more stable than scooters with smaller wheel bases. Test reports should be requested and reviewed, as the test results provide valuable information about scooter safety, performance and durability, provide objective information for scooter comparison, and can be useful when attempting to identify the most appropriate scooter for a Veteran.

**Transportation Safety:** Individuals using a scooter should have the ability to transfer independently and should transfer to a vehicle seat and stow or secure the scooter for safe transportation. A mobility device that will be used as a seat in a vehicle should be tested to and comply with RESNA WC-19, "Wheelchairs used as seats in motor vehicles." After-market seating systems (such as add-on back supports) should comply with RESNA WC-20, "Wheelchair seating systems for use in motor vehicles." There are no regulations requiring crash testing of scooters, and no scooters currently comply with the standards, therefore a scooter should not be used as a seat in a motor vehicle.

# 6.3 Performance Expectations

Minimum performance measures for HCPCS coding are outlined in **Table 4** below. *Excerpted from Local Coverage Article: Power Mobility Devices – Policy Article (A52498).*

**Table 4** Minimum Performance Measures for HCPCS Coding

| Test Results | Group 1 | Group 2 |
|---|---|---|
| Maximum Length (In) | 48 | 48 |
| Maximum Width (In) | 28 | 28 |
| Obstacle Height (MM) | 20 | 50 |
| Minimum Top Speed (MPH) | 3 | 4 |
| Range (Miles) | 5 | 10 |
| Dynamic Stability Incline (Degrees) | 6 | 7.5 |
| Fatigue Test on Level With Slats (Cycles) | 200,000 | 200,000 |
| Drop Test (Cycles) | 6,666 | 6,666 |

Additional performance measures provide critical information to determine product quality and usability including the following:

Objective test results from standards:

- Pivot width (turning radius) indicates the space required to turn the device around. This is related to the wheel position and length of the scooter.
- Total device mass determines vehicle and air transportation options and compatibility with indoor environments, especially the load capacity of the floor.
- Mass of heaviest part must be known to determine physical and functional requirements for assembly, disassembly and stowage for transportation.

Clinical performance testing can provide critical qualitative information on the following factors:

- Responsiveness indicates the behavior of the scooter when the Veteran activates the drive control.
- Fabrication quality provides insight into the quality of construction, assembly, and materials utilization and management.
- Ergonomic design for body support and transfers in and out of the device indicates how the device can be used safely and effectively by different Veterans.
- Usability for device operation, adjustments, and maintenance of all features determines necessary Veteran abilities and device limitations.

**Note:** Some scooters have enhanced features and/or capabilities that do not fit in Group 1 or Group 2 for performance requirements and respective HCPCS code descriptors. Objective lab testing to RESNA standards and thorough clinical evaluation provide critical information about device features, performance, limitations and safety considerations. FDA regulation as a Class II medical device applies.

**Care, Maintenance & Storage Requirements:** The scooter must be properly maintained to support optimal performance. All components must be kept clean and dry. When not in use, the scooter should be stored in a clean, dry indoor location. Electrical outlet access is needed for battery charging. The User Manual or Instructions for Use should clearly describe care, maintenance and storage recommendations in addition to instructions for general assembly and installation of accessories, adjustments, and device operation.

**Veteran Training Requirements:** The Veteran who is provided a scooter must receive education and training for driving on appropriate surfaces and between obstacles. Veteran training is required for transferring in and out of the scooter, and for managing moving components. Training for appropriate stowage in a vehicle, including disassembly and reassembly, is also indicated along with review of general care, maintenance and storage recommendations.

# 6.4 Limits of Use

Scooters are not intended for Veterans with significant physical impairment necessitating a wheeled mobility device for all-day use. Scooters are not appropriate for Veterans whose mobility impairments can be addressed adequately with an ambulation assistive device (e.g., cane, crutch, walker, or rollator), or who have sufficient upper limb function and cardiorespiratory endurance to propel and manage a manual wheelchair. They are also not appropriate for those who cannot transfer independently, stand and take several steps, relieve pressure independently, or require power seat functions other than power seat elevation to support physiologic functions. Scooters are not appropriate for those who use a ventilator. Use of a scooter is contraindicated for Veterans who require a wheeled mobility device to navigate in tight indoor environments (due to increased scooter length and associated turning radius) or outdoors over uneven surfaces, extreme terrain, or in inclement weather. Because scooters have not been proven to be safe when used as a seat in a motor vehicle, they are limited to being used by those who can move to a standard seat in the vehicle. Independent lab testing indicates that some scooters are limited in stability, durability, and power and control system safety, and are most likely to fail climatic (environmental) testing.

Scooters can be driven only with a tiller, and typically only maximum driving speed can be adjusted. Since scooters do not accommodate seating and positioning items, and do not include power seat functions other than power seat elevation available on some models, they are limited to those who do not require seating support. They should not be used as a seat in a motor vehicle. Only some models can be safely secured unoccupied in a vehicle. Only some models disassemble for stowing. Scooters do not accommodate Veteran weights above 600 pounds.

## 6.4.1 Performance & Limits of Use by Scooter Group

**Group 1:** Performance characteristics for minimum top speed, minimum range, obstacle height and dynamic stability on an incline indicate that the Group 1 scooters are most appropriate for either indoor or level outdoor use for limited distances. While maximum overall dimensions are the same for both scooter groups, Group 1 scooters tend to be more compact than Group 2 and some models are modular which allows disassembly for stowage and transportation. Modular scooters may be less sturdy.

**Group 2:** Performance characteristics for minimum top speed, minimum range, obstacle height and dynamic stability on an incline indicate that the Group 2 scooters are appropriate for both indoor and outdoor built environment. While maximum overall dimensions are the same for the two groups, Group 2 scooters tend to be larger than Group 1 and are more robust for navigating outdoor environments at greater distances. Disassembly for stowage and transportation is often more challenging due to device size, total device mass, and mass of heaviest part.

## 6.4.2 Limits of Use Mitigation

Limits of use for scooters are mitigated by providing a more sophisticated (higher level) wheeled mobility device – usually a power wheelchair – that can be configured and adjusted to meet comprehensive Veteran needs. Providing comprehensive Veteran education and training may partially mitigate limits of use

# 6.5 Power Operated Vehicles CLOUT Visual Dashboard

| | | | |
|---|---|---|---|
| **Outdoor Mobility** | | **Moderate** | **Very Limited** |
| **CMS Group** | | **Scooter Group 2** | **Scooter Group 1** |
| **CMS K Codes** | | **K0806 – K0808** | **K0800 – K0802** |
| **Minimum Top Speed (MPH)** | | **4** | **3** |
| **Minimum Range (Miles)** | | **10** | **5** |
| **Obstacle Height (MM)** | | **50** | **20** |
| **Drive Wheel Suspension** | | **No** | **No** |
| **Dynamic Stability Incline (Degrees)** | | **7.5 (1:10)** | **6 (1:12)** |
| **Device Features** | Expandable Controller/Alternative Controls | | |
| | Multiple Power Option | | |
| | Single Power Option | | |
| | Power Seat Elevation | | |
| | Power Standing Option | | |
| | Intended to Accommodate Seating/Positioning Items | | |
| | Backrest Angle Customizable | | |
| | Supports Tilt In Space | | |
| | Accommodates Ventilator | | |
| | Interfaces With Other Technologies (e.g., Smartphone, Communication Device, Computer, Environmental Control) | | |
| | Standard Duty (300 Lbs or Less) | | |
| | Heavy Duty (301-450 Lbs) | | |
| | Very Heavy Duty (451-600 Lbs) | | |
| | Extra Heavy Duty (601 Lbs Or More) | | |
| **Activity** | Intended For Full Time Use For Primary Mobility | | |
| | Supports Independent Propulsion In Varied Environments | | |
| | Safe As Seat During Transportation | | |
| | Can be Secured Unoccupied Inside a Vehicle | | |
| | Disassembles for Stowing (Portable Available) | | |
| **Environmental** | Indoor Mobility in the Home | | |
| | Indoor Mobility in the Community | | |
| | Outdoor Mobility in Built Environment | | |
| | Outdoor Mobility in Unbuilt Environment | | |
| | Outdoor Mobility in Inclement Weather | | |
| | Outdoor Mobility in Extreme Terrain | | |

- **Red** – common products in that category do not typically have that feature or are not typically clinically appropriate in that scenario.
- **Yellow** – a limited selection of products in that category typically have that feature, or common products in that category have limitations and may not always be clinically appropriate in that scenario.
- **Green** – most or all products in that category typically have that feature, or the most common products in that category are usually clinically appropriate in that scenario.

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# 8 Acronyms

**510(k)** Section 510(k) of the Food, Drug and Cosmetic Act requires device manufacturers who must register, to notify FDA of their intent to market a medical device at least 90 days in advance. This is known as Premarket Notification - also called PMN or 510(k). This allows FDA to determine whether the device is equivalent to a device already placed into one of the three classification categories.

**ADA** Americans with Disabilities Act, 1990

**ANSI** American National Standards Institute

**ATV** All-Terrain Vehicle

**CLOUT** Clinical Limits of Use of Tool

**CMS** Centers for Medicare & Medicaid Services

**FDA** Food and Drug Administration

**FSS** Federal Supply Schedule

**HCPCS** Healthcare Common Procedure Coding System

**HERL** Human Engineering Research Laboratories

**ICF** International Classification of Functioning

**IFU** Instructions for Use

**ISO** International Organization for Standardization

**RESNA** Rehabilitation Engineering and Assistive Technology Society of North America

**ROM** Range of Motion

**VA** Department of Veterans Affairs

**VHA** Veterans Health Administration

**WTORS** Wheelchair Tiedown and Occupant Restraint Systems

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# A Appendix A: Clinical Limits of Use Testing of the Action Trackchair



## A.1 Introduction

The purpose of this document is to provide the evaluation procedures for and describe the results of the clinical limits of use testing on the Action Trackchair (without standing feature). All tests were performed according to the methods contained within the 2009 edition of the RESNA Standards for Wheelchairs. [20] This edition was current as of the time these tests were completed.

## A.2 Clinical Evaluation

1. ***Installing and uninstalling device***
   a. Not applicable
2. ***Interface of the device while person is using it (seating and positioning)***
   a. The user's manual states that the device should be professionally set up for client. The average therapist would need training in order to set this up appropriately for a client.
   b. The Action Trackchair has a seat frame that is integral to the design and which has limited adjustability.
   c. A flat pan can be ordered for installation of a custom cushion. The standard cushion is bolted to the frame.

d. The backrest has a fixed seat to back angle of about 5 degrees, and therefore the frame of the backrest may limit the types of backrests that can be mounted unless custom mounting was used. Limited seating options are available because of this design.

e. If excessive hip abduction occurs, the lateral thighs may rest against the armrests and cause skin breakdown.

f. About 20 degrees of anterior and posterior tilt is present in the seat. A user could slide from the chair and fall forward out of the device if the seat is in anterior tilt and the user is not wearing seat belt or is driving downhill.

g. A seatbelt is provided. The user's manual states that either a seatbelt or harness is required at all times. From our experience, a harness would need to be worn with a seatbelt; otherwise the user could slide out from under the seatbelt. A loose seatbelt can also get caught in the treads and can serious injury the client.

h. Two pins on both sides (4 total) are to be used to secure the leg platform. However, theoretically a user can lower the foot platform far enough such that it is possible to insert just one pin on each side in the foot platform. This could cause the foot platform to be less secure. It is also possible to pull the leg platform out far enough such that, if a pin is placed, it would not insert into a hole and the leg platform could fall out. The leg platform should have a color painted on it to indicate how far it can be inserted or pulled out.

i. Only 14.5" to 19.5" leg length is available, depending on placement of pins in leg platform.

j. Only 16-24" or 18-20" seat widths are available, depending on model.

k. Only 16.5" or 20" seat depths are available.

l. Other important measurements are listed on a spec sheet on page 13 of the user's manual.

m. Armrests are not height adjustable.

n. A client's hand can get caught between treads and a wheel. Loose clothing or a seat belt can get caught. It appears that clothing guards are available. No shrouding is available. However, both of these solutions would potentially impede transfers.

o. A user's foot can get caught behind the foot platform and in front of batteries, especially if the seat is in rearward tilt. Then, if the user tilts anteriorly, he or she could crush the feet. The issue may be a more serious issue for someone with knee flexion contractures. Calf pads or shoe holders could mitigate this risk. Shoe holders could however place the user in danger if the device tipped over.

p. The user cannot change the angle of the foot platform or knee hanger angle to accommodate contractures.

q. The seat wobbles forward and backward on the base in any of the positions of tilt or neutral which makes seating feel a bit unstable.

***3. Engagement or disengagement of the person with the device (transfers)***

a. The Action Trackchair is a large device relative to other powered mobility devices. Transfers are likely to be more challenging as a result.

b. Armrests swing up and backwards, allowing transfers into the device. The seat also has forward and rear tilt which can allow the seat to be in various positions for the transfer. Transferring from the side requires transferring over treads which could cause shear over skin.

c. Transferring the cushion from a wheelchair to the device would be difficult and therefore a second cushion is likely necessary.

d. Several transfer methods are possible:

   1. Sliding board transfer – a side to side transfer using a sliding board would require a transfer of about 28 inches laterally because of the width of treads. A transfer board with minimum of 30 inch would be needed. This requires up and downhill transfers and trunk control to complete independently. The tread actually helps provide friction on the sliding board to keep it in place to some extent. Transfers can also be done at an angle but may be challenging due to the distance and the presence of the foot platform.

   2. Hoyer lift – this would be difficult because of the width of the device. The total width from tread to tread is 39 inches, which may be too far apart for the legs of a Hoyer lift. An overhead ceiling lift would therefore be needed for a person who requires a dependent lift with a device. However, the device would not likely fit inside the home due to its width, and a lift would therefore need to be in a garage, etc.

   3. Two-person lift – a two-person lift could be accomplished using one person in front and one person in back of the client. However, this position causes the person in the back to be obstructed by the armrest and limits foot clearance for the person doing the lifting from the front. Therefore, caregivers could be injured as a result of the transfer ergonomics.

   4. Stand pivot - the user can also stand pivot into the chair. The safest way to do this would be to remove the foot platform completely before transferring. However, the foot platform requires some time for removal. If the client cannot bear weight or take steps during a stand pivot, this may be a difficult transfer for the caregiver because of the distance a wheelchair would need to be placed away from the device due to the treads. The person helping the client transfer into the chair would need to hold the person in order to keep him/her from falling out of the chair until he or she is tilted back. A handle is present on the armrest which is helpful to assist this process.

e. Foot platform does not easily flip or swing away to accommodate transfers. But pins can be removed to completely remove footplate. The process requires full hand function to remove pins. Reinstalling the foot platform is a bimanual task.

***4. Usage***

a. User's manual: included in paper format with text, but is not available in accessible formats. Reading level may be higher than what users can comprehend.

b. Potential technical or safety issues during usage:

1. If the foot platform is set at lowest level, and the seat is tilted forward, the foot platform could potentially stop the chair or catch on the ground, which could cause the client to fall forward out of the chair. This is an even bigger problem if going uphill.
2. User-operated joystick and attendant control interface are available. Alternative controls like sip and puff or head array control systems are not available. The company does support a chin control accessory, add on switches, goal post joystick and different types of control switches for the light and tilt functions.
3. The switch that controls the tilt function is typically mounted to the armrest. A better location for the switch control for the tilt function could be the top of the transfer handle for easier access but this could also be accidentally hit during transfers or other movements.
4. Turning the joystick off does not turn off the tilt switch. This violates ISO Section 14, Part 8.9 (Drive inhibit during charging). There is no lockout value for how much tilt can be in place to be able to drive.
5. A headrest is not provided as part of the default package. This could cause injury if stopping suddenly.
6. A person would need excellent peripheral vision to ensure he/she has enough lateral clearance while driving, due to wide width of chair.
7. Corrosion/salt water may cause failures.
8. The battery is close to the ground, so if driving through water this could cause electrical failure or pose safety risks to users.
9. The device may not pass Section 14 of ISO because the charger is plugged into the device while the device is being driven, which violates Part 8.9 (Drive inhibit during charging).
10. The electrical cord on back of device could get caught on brush or other items on the ground while driving.
11. The turning radius is tight despite the width of the overall device.
12. Metal frame could be dangerous if an electrical issue occurred.
13. Changing battery may require disassembling the device by removing the seat.
14. From our perspective, it is recommended that a user does not drive alone and that someone is always present.
15. The device can be disengaged if batteries die, but the user's manual states it cannot be dragged passively more than 4mph. However, it appears that it cannot be disengaged if the tilt is in rearward position when batteries die. The device is too heavy for a person to drag manually.
16. The user's manual states that the device should not be driven on slopes above 20 degrees. The average user may not be able to judge a 20 degree slope.
17. Rear tilt causes the charger cable plug to be crushed under the seat frame.

c. Supplies needed for usage: none

d. Body Structures/Functions needed to use the device: Bimanual hand function is needed for installing the foot platform. Adequate vision is needed for driving. Trunk control, depending on the type of transfer mechanism used, may be necessary. Hand function is needed to operate the joystick and switch.

e. Role of therapist in usage: A therapist is recommended for training both for managing parts, set up, and driving training.

***5. Maintenance Protocols***

a. The user's manual states that the device should be cleaned with a hose after use where it is covered in dirt and/or mud. Care should be taken to not spray the motor controller, which is located under the seat, and also a plastic bag should be placed over the joystick to ensure water does not damage the internal components.

***6. Stowing and transportation***

a. Will require utility ramps and wide trailer for transport.

## A.3 Non-Destructive Engineering Testing

***1. Conditions of testing:***

a. Date: June 22, 2017 14:00

b. Battery status: Full device battery

c. Temperature: 87 degrees F

d. Weather: Chance thunderstorms (encountered during testing)

***2. Tests performed***

a. *WC-02 Determination of Dynamic stability*

1. The device is very stable over most slopes. Even though it significantly tilts and tips, no unsafe situations were encountered on slopes of up to 20 degrees.
2. It is capable of turning 360 degrees on a 20 degree slope without stability or traction/power issues.
3. No indication that muddy 20 degree slope reduced maneuverability of chair.
4. The chair remains dynamically stable even when maneuvering on a 20 degree slope with sub-optimal seat tilt angles.

b. *WC-04 Determination of Maximum Range*

1. This testing was performed using the procedures outlined in the WC-04 standard; however, the test was modified to include a non-standard surface (grass). This likely provides a more accurate estimate of the Trackchair's range when used outdoors.
2. Grass – 25.7km.
3. Hard surface – 32.7km.

c. *WC-10 Max Obstacle Climb*

1. The manufacturer's test report indicates that a 75mm (3") climb is possible.
   i. Enhanced testing did not measure the exact limit of climbing ability, but the mechanical limit is significantly (>2x) higher than the reported maximum climb.

2. The device is susceptible to being caught on obstacles narrower than the track width. The battery box is what usually catches on obstacles. This was experienced in the evaluation when driving through a deep puddle and muddy area. One track sunk into mud, and the battery box caught the edge of the puddle, stopping forward motion.
3. The rear anti tip wheels may also contribute to being stuck on obstacles. They may contact surfaces and lower the traction force on the treads, which can lead to spinning and not contacting the surface.
4. The device did get stuck when climbing over a ~2" log (one track only) on a 20 degree slope. Reversing was still possible to get out of the situation.
5. We attempted to stop the tracks by placing a stick between the track and wheels. The stick was broken and fell out of tracks, and full functionality returned.
6. No indication during tests that tall grass or other similar obstacles posed danger of stopping the device.

d. *Drag Test* – Given that the Action Trackchair is marketed for outdoor recreational activities such as hunting, it is not unforeseeable that chair may be used to drag or pull items with rope.
   1. Chair had no issue dragging 2 hay bales (approx. 80-100 lb) through various obstacles.
   2. Climbing loose dirt hill did cause tracks to spin while pulling hay bales, but the chair was still able to climb.

e. *Outdoor Obstacle Climb*
   1. The chair is capable of climbing over log piles and similar obstacles, but care must be taken to ensure the operator does not drive too fast; otherwise, there is a risk of being thrown out of the seat, or injured by a strong rocking motion if seat belted in.
   2. The tilting seat function is necessary in some cases to overcome obstacles. In most cases, foot support clearance is the reason (and not stability) for increased risk of tipping.

f. *General Outdoor Navigation*
   1. Moisture
      i. Some squeaking heard in track assembly after rainstorm, but function remained normal.
   2. Temperature
      i. During testing the joystick indicated a high temperature warning. This went away immediately, but returned during movement. The motors were dangerously (to human touch) hot.
      ii. At one point during testing, the chair was unable to turn due to overheated motors. It eventually slowed down significantly, but immediately still allowed forward movement after stopping for a few seconds.
      iii. An operator indicated the controller was also hot from use, but not dangerously hot like the motors.
      iv. After 2 minutes of rest after overheating, the chair was restarted and regained full function for 360 turns, etc. However, the temperature warning returned.
      v. The chair stopped due to overheating on a 20 degree slope.
      vi. The chair was veering to one side due to overheating of motors. This is not uncommon with overheated motors in power wheelchair configurations.
   3. Braking
      i. If braking downhill with sub-optimal seating position (upright), the device is still stable. The chair seems to begin tipping, but does not actually tip.
      ii. It demonstrated very good stability when braking downhill while facing uphill (braking in reverse) with sub-optimal seat position. In this situation, the chair's stability seemed to exceed the operator's sense of safety.
   4. Battery
      i. After 1 hour of evaluation, one bar was off from fully charged on battery indicator.
   5. Other
      i. One of the rear anti tip wheels came loose during testing. The same wheel was initially tight and did not roll before test began.

## A.4 Destructive Engineering Testing

Durability testing: The manufacturer provided an independent test report indicating that the chair passed the Section 8 durability test. While this is an important bench mark, it should be noted that this test is meant to represent the minimum acceptable standard for everyday mobility and might not be representative of use in extreme outdoor terrain. No consensus standards exist for testing mobility devices in extreme outdoor terrain, so the chair will have to be judged on durability based on performance of devices in the field, over time. Many cyclic related failures have early warning signs, such as loose hardware, excessive corrosion, bent components, cracks in metal welds or tubes, degradation of wire coverings, excessive wear, or excessively wobbly hinges. It is recommended that end users and/or caregivers be taught how inspect the chair for these signs and to do so prior to each use.

# B Appendix B: Clinical Limits of Use Testing of the Rio Mobility Firefly



## B.1 Introduction

The purpose of this document is to describe the evaluation procedures for and results of the limits of use testing on the Firefly Electric Handcycle (Rio Mobility, San Francisco, CA). The Firefly has characteristics of both a manual wheelchair and a power wheelchair. For this evaluation, the Firefly was paired with a Crossfire T7A (Top End, Pinellas Park, FL) Cantilever frame manual wheelchair, which was previously tested by HERL and has passed RESNA wheelchair standards as a stand-alone device. All tests were performed according to the methods contained within the 2009 edition of the RESNA Standards for Wheelchairs. [20] This edition was current as of the time these tests were completed.

## B.2 Clinical Evaluation

***1. Installing and uninstalling device***

a. Installation instructions: no installation instruction manual accompanied the device.

b. Users are instructed to watch a YouTube video (https://www.youtube.com/watch?v=Uspd92VgDsY).

c. The YouTube video does not have sound other than music and is not in accessible format. The video shows a user installing the device with some help from an additional person. The video actually runs quite fast and would have to be paused many times in order to complete tasks. The video shows some tasks without providing sufficient information, e.g., tires being inflated but does not designate pressure. The video does not show anti-tippers on the chair during installation despite the fact that the user's manual states that anti-tippers must be used at all times. Green or red marks are shown to indicate right and wrong way to perform tasks, but this may not be intuitive.

d. The user's manual recommends that a bicycle or wheelchair mechanic installs the device, but the device is sold directly to consumer and video shows the user doing most of the installation.

e. The installation process

    1. This involves many tasks, each involving one or multiple steps.

f. Space requirements

    1. It is estimated that 6x6 foot space be available for installation

g. Body structures and functions needed

    1. If installing without assistance, normal upper limb function and good trunk control are required.
    2. Arm strength is necessary to lift device while installing.
    3. Good trunk control is needed if installing battery or components while seated in the chair.
    4. Pincer grasp is needed to hold tools.
    5. Crouching or sitting on floor is needed for parts of installation conducted while outside of chair.
    6. Bimanual tasks are required.
    7. Reasonable near-sight vision needed for small parts.
    8. Good fine motor skills, grasp strength, and sensation needed to manipulate tools and parts.
    9. The Veteran must be sitting in chair to weigh it down when performing some of the tasks.

h. Parts/Components needed for installation

    1. Installation requires multiple parts, many of which are small and could be lost if dropped

i. Compatibility of parts

    1. The device would not be compatible with folding frame chairs. The user is referred to the website for information about frame compatibility. Some of the information on the website is incomplete. No information is given to explain that this device cannot be installed on hangers of removable legrests.
    2. The video shows that mounting collars need to be level when attached to the frame. But this is not possible if the frame is tapered.

j. Supplies needed for installation

    1. Video shows that a ruler is needed, but the task involved requires leveling, so the appropriate tool is really a bubble level.

k. Therapist role in installation

    1. It is recommended that this device should not be installed by a Veteran, but rather by a qualified therapist or rehab engineer.

l. Potential safety issues during installation

    1. Two small blocks are provided to lift casters to an appropriate height above ground. These are about 4x4x2 in, and casters can easily roll off block while adjusting the height. This could cause an injury if a person is sitting in the chair when it falls off the block.
    2. Many of the tasks of installation involve rough or sharp parts that could scrape or cut the hands, and many "pinch points" exist on the device that are not marked and could cause hand injury.
    3. Wheel lock may be in the way when tightening bolts and would need to be unlocked to move it out the way, which then could cause the chair to roll unexpectedly.

***2. Interface of the device while person is using it (seating and positioning)***

a. The user's manual recommends that anti-tippers be used at all times. Therefore, Veterans who do not typically use anti-tippers would need to remove them after using the Firefly.

b. The user manual recommends that the axle be set rearward for stability. Therefore, Veterans who typically have a forward positioned axle will need to adjust the axle before using the manual wheelchair on its own.

***3. Engagement or disengagement of the person with the device (transfers)***

a. The Firefly occludes portions of the front of the wheelchair seat. Transfers are likely to be more challenging or impossible when the device is attached. Therefore, transfers should not be conducted unless the device is removed.

b. If the device is completely removed, transfers are not affected.

c. Transferring with device removed except for collars left on legrests could cause skin breakdown.

***4. Usage***

a. User's manual

    1. The manual is included in paper format with text, but is not available in accessible formats. Reading level may be higher than what some users can comprehend e.g. refers to "center of gravity," etc.
    2. The manual says that there is a return spring in the front wheel to keep it from swiveling but there is not.
    3. The manual recommends bike helmet but evaluators recommend motorcycle helmet given potential for high speed and impact.

b. Potential technical or safety issues during usage

1. The key easily falls out of battery while device is in use, and if lost, battery cannot be removed. The key would therefore need to be tethered.
2. Leaving clamps on legrests makes each installation easier, but a Veteran could get skin breakdown because it could press up against leg or scrape against it while transferring. It has a sharp edge to it. This is a bigger problem when the legs are tapered.
3. The user's manual does not state footrests are needed or that a user should wear shoes to prevent injury; however, lack of footrests or not wearing shoes could cause serious hard to the feet if they get caught on the ground during use.
4. Front wheel may slip if the axle isn't set far enough back or if the front wheel is too far away from footrests.
5. When climbing hills, the Veteran may need to lean forward which could cause the Veteran to fall out of the chair.
6. The device may seem like it is latched when it is really not. Could therefore drive off with the device not installed and it could then fall off.
7. Front wheel swivels and cannot be locked in forward position.
8. When putting the device on or taking it off a chair, the handle bars turn and may hit the Veteran in the abdomen.
9. Stopping on hill may be dangerous because Veteran could roll backwards if Veteran does not use wheel locks or hold brakes.
10. To turn off the device, the Veteran must turn off the display and also the battery. It is possible that the Veteran may think that turning off the display is enough and may leave battery on, which could drain battery.
11. The device drives like a bike, not a scooter, so it takes some learning if used to a scooter.
    i. The device does not limit the maximum speed when traveling down a slope unless the throttle is engaged. The maximum speed downhill can be much higher than the maximum speed on a horizontal surface. Further, if the throttle is re-engaged while traveling at speed, the motor controller slowly ramps up the assistance, which can cause a brief slow down as the motor catches up to the chair's forward speed.
    ii. The braking system of the Firefly does not automatically engage. The operator must apply the brakes using a bicycle brake lever to come to a stop. Simply releasing the throttle causes the device to coast down slowly, and at high speed the device will travel for very long distances (>100m) before coasting to a stop.
    iii. Operating the throttle lever in the opposite direction of travel does not slow or stop the Firefly device. In a typical powered wheelchair or scooter this will bring the device to a stop and then reverse direction. The lack of this feature may present an unsafe situation for someone used to operating a power wheelchair because the device will not respond at all to reverse throttle inputs until the Firefly has come to a complete stop. This control system makes low speed maneuvers such as opening and traveling through a door much different than performing the same maneuvers with a power wheelchair, and proper instruction is important to ensure the safety of the occupant.
12. The device may compromise the lateral stability of the manual wheelchair.

c. Supplies needed for usage

1. The Firefly is water resistant but not waterproof. If caught in the rain the Veteran would have to cover battery and controller with a plastic bag. Therefore, the Veteran would need to carry a bag if expecting inclement weather

d. Body Structures/Functions needed to use the device

1. Bimanual hand function and upper limb function need to control handcycle.
2. Adequate vision is required for driving.
3. Removing device requires bimanual hand function to prevent the chair from falling to the floor.

e. Role of therapist in usage

1. Learning to put it on a wheelchair and take it off requires a lot of practice and safety. A therapist is recommended for training both for attaching and removing device before/after each use and also for driving.
2. Direct to consumer sale could result in a Veteran receiving the device and not being able to safely install, maintain, or use the device. Therefore, it is recommended that a therapist be involved in an appropriate clinical evaluation for this device.

***5. Maintenance protocols***

a. No maintenance protocols were provided by the manufacturer.

***6. Stowing and transportation considerations***

a. Stowing and transportation of an unattached device will require adequate space in a vehicle trunk or on the car seat and adequate strength to lift the device if not attached to the wheelchair.

b. If attached to the wheelchair the entire system would need to be transported in a vehicle such as a van or pickup truck and therefore a ramp may be needed.

# B.3 Non-Destructive Engineering Testing

***1. Conditions of testing***

a. Start Date: May 18, 2017

b. Battery status: Full device battery

c. Temperature: 70 degrees F

d. Weather: For outdoor testing, all tests were performed according to RESNA standards. Most testing occurred indoors, making this mostly a non-issue however.

***2. The following RESNA tests were performed unmodified with the Firefly attached to the Crossfire T7A. Results of these tests were compared to previous results of the stand-alone Crossfire T7A as applicable.***

a. *WC-01 Determination of Static Stability*

1. Due to the 3-wheeled configuration with the Firefly device installed, the forward static stability tests do not apply. There are no anti-tip devices installed, so those tests cannot be completed.

**Table 5** WC-01 Determination of Static Stability

Test performed by: B Gebrosky
Date: 6/14/2017
Rev: A

| **Stability Direction** | | **With Firefly** | | | | **Without Firefly** | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | **Tipping Angle** | | | | **Tipping Angle** | | | |
| | | **Least Stable** | | **Most Stable** | | **Least Stable** | | **Most Stable** | |
| Forward | Front wheels locked | 9.3 | N/A | 9.5 | N/A | 9.3 | N/A | 9.5 | N/A |
| | Front wheels unlocked | 9.2 | N/A | 9.4 | N/A | 9.2 | 14.9 | 9.4 | 28.2 |
| Rearward | Rear wheels locked | 10.3 | 5.5 | 10.5 | 21 | 10.3 | 6 | 10.5 | 6.6 |
| | Rear wheels unlocked | 10.2 | 5.5 | 10.4 | 24 | 10.2 | 11.5 | 10.4 | 26.6 |
| | Anti-tip devices ① | 11.2 | N/A | 11.3 | N/A | 11.2 | 15.9 | 11.3 | 30 |
| Sideways | Left | 12.1 | 19 | 12.2 | 18 | 12.1 | 19.7 | 12.2 | 26 |
| | Right | 12.1 | 20 | 12.2 | 17 | 12.1 | 19.2 | 12.2 | 24.3 |

① "Least stable" and "most stable" refer to the positioning of the anti-tip devices. (See 11.2.3 and 11.3.2)

**Note:** This device was not evaluated in the forward direction due to the 'tricycle' three wheeled design. The t7a model that was shipped for firefly testing was not equipped with anti-tip devices, while the previously tested model did come equipped with those devices.

b. *WC-02 Determination of Dynamic stability*

1. Dynamic stability testing of the Firefly device was modified from the originally specified methods in the RESNA standards due to the differences in the control system of the Firefly versus a typical power wheelchair or scooter type device. Due to the lack of automatic braking, or failsafe braking in the case of a power off event, the only stopping method was using the supplied hand brakes. Both brakes were engaged fully for each event evaluated.

**Table 6** WC-02: Dynamic Stability

Test Performed by: B. Gebrosky
Date: 5/30/17
Rev: A

| Description | Test | Anti-Tip Devices | Method of Retardation | Stability Score Ramp Angle (°) | | | | Comments |
|---|---|---|---|---|---|---|---|---|
| | | | | 0 | 3 | 6 | 10 | |
| Rearward Dynamic Stability | 8.2 Starting Forwards | With Anti-Tip Devices | — | N/A | N/A | N/A | N/A | — |
| | | Without Anti-Tip Devices | — | 3 | 3 | 3 | 3 | Significant Spin/Rearward Slide @ 6° |
| | 8.3 Stopping After Traveling Forwards | With Anti-Tip Devices | R Release | N/A | N/A | N/A | N/A | |
| | | | P Power Off | N/A | N/A | N/A | N/A | |
| | | | A Applying Reverse | N/A | N/A | N/A | N/A | |
| | | Without Anti-Tip Devices | Hand Brakes | 3 | 3 | 3 | 3 | Sliding Backwards After Stop @ 6° |
| | | | P Power Off | N/A | N/A | N/A | N/A | |
| | | | A Applying Reverse | N/A | N/A | N/A | N/A | |
| | 8.4 Braking When Traveling Backwards | With Anti-Tip Devices | R Release | N/A | N/A | N/A | N/A | |
| | | | P Power Off | N/A | N/A | N/A | N/A | |
| | | | A Applying Reverse | N/A | N/A | N/A | N/A | |
| | | Without Anti-Tip Devices | Hand Brakes | 3 | 3 | 0 | 0 | @ 6° No Stop, Grabbing Handrims Causes Rearward Tip |
| | | | P Power Off | N/A | N/A | N/A | N/A | — |
| | | | A Applying Reverse | N/A | N/A | N/A | N/A | — |
| Forward Dynamic Stability | 9.2 Braking When Traveling Forwards | | Hand Brakes | 3 | 3 | 3 | 3 | Skid |
| | | | P Power Off | N/A | N/A | N/A | N/A | — |
| | | | A Applying Reverse | N/A | N/A | N/A | N/A | — |
| | 9.3 Traveling Forward Down a Slope onto a Horizontal Surface | | N/A | 3 | 3 | 3 | — | — |
| Dynamic Stability in Lateral Directions | 10.2 Turning on a Slope | N/A | N/A | 3 | 3 | 3 | 3 | — |
| | 10.3 Turing in a Circle at Maximum Speed (Minimum Diameter, in Meters) | N/A | N/A | 1.69 | N/A | N/A | N/A | — |
| | 10.4 Turning Suddenly at Maximum Speed | N/A | N/A | 0 | N/A | N/A | N/A | Immediate Tip w/o Operator Intervention |

| Description | Test | Stability Score Ramp Angle (°) | | | Comments |
|---|---|---|---|---|---|
| | | 12mm | 25mm | 50mm | |
| Step Transitions | 8.5 Traveling Forward Up a Step Transition | 3 | 3 | 3 | — |
| | 8.6 Traveling Backward Down a Step Transition | 3 | 3 | 3 | — |
| | 9.5 Traveling Forward Down a Step Transition (from Standing Start) | 3 | 3 | 3 | — |
| | 10.5 One Side of Wheelchair Drops Down Step Transition | 3 | 3 | 3 | — |

**Note:** This device has no automatic braking systems. Maximum speed is only limited when the throttle is active. The device relies solely upon the hand brakes to come to a stop.

c. *WC-03 Determination of Effectiveness of Brakes*

1. Similar to the modifications in WC-02, the hand brakes were the only method evaluated for measuring the stopping distances of the Firefly.

**Table 7** WC-03 Test Methods and Requirements for the Effectiveness of Brakes

Test Performed by: B. Gebrosky
Date: 6/1/2017
Rev: A

| **Brake Type** | | **Method of Operation** | **Operating Force Needed** | | |
|---|---|---|---|---|---|
| **Hand** | **Disc** | **Hand** | **49N** | | |
| **Brake Performance Test Procedures Running Brakes** | | | | | |
| **Test Plane Inclination** | **Direction of Travel** | | **Hand Brakes (m)** | | |
| Horizontal | Forward | Min Braking Distance (m) | 3.23 | 2.74 | 2.59 |
| | Reverse | Min Braking Distance (m) | 0.51 | 0.53 | 0.56 |
| 3 degrees | Forward | Min Braking Distance (m) | 3.30 | 3.15 | 3.66 |
| | Reverse | Min Braking Distance (m) | 1.63 | 1.52 | 1.63 |
| 6 degrees | Forward | Min Braking Distance (m) | 3.96 | 4.88 | 4.52 |
| | Reverse | Min Braking Distance (m) | 4.70 | 4.11 | 5.03 |
| 10 degrees | Forward | Min Braking Distance (m) | The 10 degree braking tests were not performed due to the tiller overpowering the clamps (at proper torque) and rotating during heavy braking. | | |
| | Reverse | Min Braking Distance (m) | | | |

d. *WC-04 Max Range*

1. Due to the dangers present in modifying lithium battery systems, the range test for the Firefly was modified by driving until the motor would no longer provide any assist to the wheelchair. The range test was then recorded as this value and not calculated using current consumption, battery capacity, and distance traveled.

**Table 8** WC-04 Determination of Energy Consumption of Electric Wheelchairs and Scooters - Theoretical Range

Wheelchair Information
Test Performed by: B Gebrosky
Date: 6/14/17
Test Dummy Mass: 113kg.
Rev: B

| **Description** | | **Value** | |
|---|---|---|---|
| Battery Information | C5 Capacity (Ah) | 6.6 | Provided _X_ Calculated _____ (Choose One) |
| | Nominal Voltage* (V) | 36 | *Combined Voltage of Set if Multiple Batteries |
| | Calculated Energy Capacity (Wh) | 237.6 | = C5 X Nominal Voltage (Sheet Will Calculate if Above is Provided) |
| | Chemistry Composition (Include Subtype) | Lithium Ion (Cobalt) | |
| | Size (Group or Approximate Dimensions in mm) | Not Specified, Composed of 18650 Lithium Ion Cells | |
| Track Information | Centerline Distance (m) | 123.76m | |
| | Long Leg Length (m) | 44.20m | |
| | Short Leg Length (m) | 17.68m | |
| | Surface Description | Smooth Concrete. Top Coated | |
| Test Information | Controller Setting Adjustments Made (Sec. 6.1) | None, Used Speed "5" Setting. Coasting and Braking Required to Negotiate Turns. | |
| | Wheelchair Occupant | Human _X_ Dummy_____ (Choose One) | |
| Test Results 7.1 Continuous Driving Test | Total Energy Consumed (Wh) | Not Measured | |
| | Specific Energy Consumed (Wh/km) | — | |
| | Calculated Range (km) | 16.84km | |

**Note:** Due to lithium chemistry, capacity rating was assumed to be C5 rating. No further information available for this battery. Device was tested from full charge until the battery set completely drained and would no longer provide power assist to the wheelchair. Because of this modification, the total energy consumed was not measured during the test.

e. *WC-05 Determination of Overall Dimensions, Mass, and Turning Space*

1. The Firefly does not seem to have an explicitly listed weight limit. We tested it with the max load of the T7A, which is 250 lbs, but other chairs that are approved for it have higher weigh capacities (TILite Aero Z 265 lbs for example). The website for the Firefly has a "compatibility check" but does not explicitly list maximum weight.
2. Also included below are the results found for the Top End Crossfire T7a without the Firefly device installed.

| Notable Dimensions | Crossfire T7a | W/Firefly |
|---|---|---|
| Length (mm) | 850 | 1430 |
| Width (mm) | 647 | 650 |
| Minimum Height for Transport(mm) | 462 | 950 |
| Propelling Wheel Diameter (mm) | 610 | 610 |
| Caster Wheel Diameter (mm) | 122 | 100 |
| Handrim Diameter (mm) | 535 | 550 |
| Mass (kg) | 12 | 23 |
| Mass of Heaviest Component (kg) | 6 | 7 |
| Minimum Turning Diameter (mm) | 1407 | 1900 |
| Minimum Pivot Width (mm) | 987 | 1550 |
| Minimum Doorway Entry Depth (mm) | 950 | 1350 |
| Corridor Width for Side Opening (mm) – Entering | 710 | 1250 |
| Corridor Width for Side Opening (mm) – Exiting | 730 | 1350 |

f. *WC-06 Max Speed*

**Table 9** WC-06 Determination of Maximum Speed, Acceleration and Deceleration of Electric Wheelchairs

Testing Performed by: B Gebrosky
Date: 8/8/2017
Rev: A

| All Controller Settings at Maximum | | Normal Operation | Emergency Reverse | Emergency Power Off |
|---|---|---|---|---|
| Maximum Speed (Vm) m/s | Forwards Horizontal | 5.30 | — | — |
| | Forwards Uphill 3 Degree Ramp | 4.42 | — | — |
| | Forwards Uphill 6 Degree Ramp | 2.44 | — | — |
| | Forwards Downhill 3 Degree Ramp | 5.57 | — | — |
| | Forwards Downhill 6 Degree Ramp | 6.15 | — | — |
| | Rearwards Horizontal | 1.28 | — | — |
| Horizontal Acceleration m/s/s | Maximum A | 0.96 | — | — |
| Horizontal Deceleration m/s/s | Maximum D | 3.18 | — | — |

**Note:** Emergency reverse and power off were not performed due to hand brake configuration.

g. *WC-07 Method of Measurement of Seating and Wheel Dimensions, Parts 1,5,6, and 12*

**Table 10** WC-07 Method of Measurement of Seating And Wheel Dimensions

Test Performed by: Zach Edelmann, Sam Waters
Date: 5/18/17
Rev: A

**Measurements**

| | Dimension Description | Fixed or Minimum Value | Maximum if Relevant | Number of Increments |
|---|---|---|---|---|
| 1 | Seat Plane Angle | 23 | 24 | 13 |
| 2 | Effective Seat Depth | 410 | 395 | 13 |
| 3 | Seat Width | 450 | — | — |
| 4 | Effective Seat Width | 500 | — | — |
| 5 | Seat Surface Height at Front Edge | 495 | 520 | 13 |
| 6 | Backrest Angle | 13 | 28 | 13 |
| 7 | Backrest Height | 270 | 265 | 13 |
| 8 | Backrest Width | 450 | — | — |
| 9 | Headrest in Front of Backrest | N/A | — | — |
| 10 | Headrest Height Above Seat | N/A | — | — |
| 11 | Footrest to Seat | 390 | 405 | 13 |
| 12 | Footrest Clearance | 100 | — | — |
| 13 | Footrest Length | 150 | — | — |
| 14 | Footrest to Leg Angle | 78 | 65 | 13 |
| 15 | Leg to Seat Surface Angle | 101 | 82 | 13 |
| 16 | Armrest Height | 275 | 285 | 13 |
| 17 | Front of Armrest to Backrest | 290 | 340 | 13 |
| 18 | Armrest Length | 220 | — | — |
| 19 | Armrest Width | 30 | — | — |
| 20 | Armrest Angle | 3 | 24 | 13 |
| 21 | Distance Between Armrests | 450 | — | — |
| 22 | Front Location of Armrest Structure | 290 | 270 | 13 |
| 23 | Hand Rim Diameter | 550 | — | — |
| 24 | Propelling Wheel Diameter | 610 | — | — |
| 25 | Horizontal Location of Wheel Axle | 100 | — | — |
| 26 | Vertical Location of Wheel Axle | 110 | — | — |
| 27 | Caster Wheel Diameter | 100 | — | — |

h. *WC-8 Fatigue*

**Table 11** WC-08 Static, Impact And Fatigue Strengths

Testing Performed by: B Gebrosky
Date: 8/14/2017
Rev: A

| Description | | Force Applied (N) | Pass/Fail |
|---|---|---|---|
| Static | 8.4 Armrest Resistance to Downward Forces | N/A | N/A |
| | 8.5 Footrest Resistance to Downward Forces | N/A | N/A |
| | 8.6 Tipping Levers | N/A | N/A |
| | 8.7 Handgrips | N/A | N/A |
| | 8.8 Armrest Resistance to Upward Forces | N/A | N/A |
| | 8.9 Footrest Resistance to Upward Forces | N/A | N/A |
| | 8.10 Push Handles Resistance to Upward Load | N/A | N/A |
| Impact | 9.3 Backrest Resistance to Impact | | N/A |
| | 9.4 Handrim Resistance to Impact | | N/A |
| | 9.5 Casters Resistance to Impact | | N/A |
| | 9.6 Footrest Resistance to Impact | | — |
| | 9.6.3 Lateral Impact | | N/A |
| | 9.6.4 Longitudinal Impact Front Structure Resistance to Impact | | N/A |
| | 9.7.2 Frontal Impact | | ISO Only |
| | 9.7.3 Offset Impact | | ISO Only |
| Fatigue | 10.4 Two-Drum Test | 200,004 Cycles | Pass |
| | 10.4.3 Preliminary Current Measurement | — | — |
| | 10.5 Curb Drop Test | 6,666 Cycles | Pass |

i. *WC-10 Max Obstacle Climb*

**Table 12** WC-10 Determination of Obstacle-Climbing Ability of Electric Wheelchairs

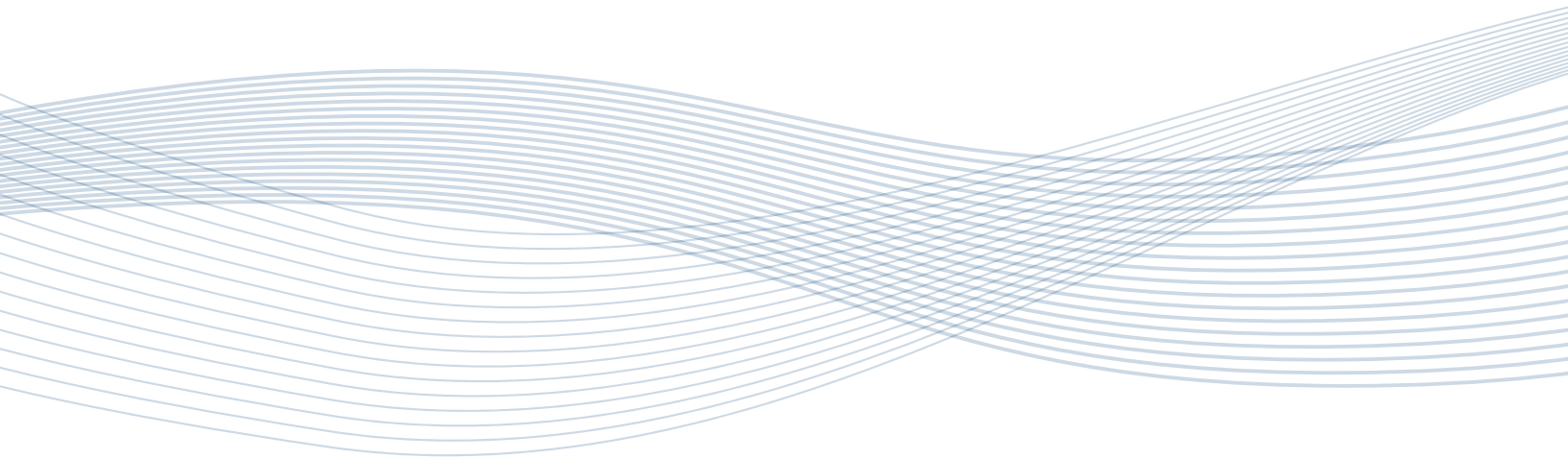
Testing Performed by: S. O'Donnell
Date: 8/1/2017
Rev: A

| Sec. | Obstacle Climbing | Obstacle Ht. (mm) |
|---|---|---|
| 7.1 | Forwards, No Run-Up | 45 |
| 7.2 | Backwards, No Run-Up | 18 |
| 7.3 | Forwards, .5m Run-Up | 90 |
| 7.4 | Backwards, .5m Run-Up | 45 |

| Sec. | Obstacle Descending | Obstacle Ht. (mm) |
|---|---|---|
| 7.5 | Forward (Use Height in Sec. 7.1) 1m Run-Up | 90 |
| 7.6 | Backwards, 1m Run Up, Slow Speed | 45 |

j. *WC-14 Max Thermal Drive*

1. This test was not performed due to durability and safety concerns when collecting the data. There is significant wheel spin involved due to the lack of traction when climbing a 6 degree slope which at the very least will make the data unreliable as compared to a typical max thermal test.

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