Permobil AB

Title: Human Factor Validation of Pediatric Mobility Device

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Explorer Mini Human Validation Test Protocol

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2 Background

The theoretical foundations behind early mobility draws its roots from empirical research in the 1950s where the interplay between physiology and psychology was investigated. A line of seminal works showed the cognitive processes that are 'born' and nurtured when toddlers begin to be mobile. The implications of immobility or inefficient mobility in toddlers with physical disabilities were particularly drawn to attention by Butler and colleagues in the 1980s when modified power wheelchairs (PWC) were trialed on toddlers. Early trials focused on testing whether toddlers can learn to use PMT, but as it became established that toddlers can indeed learn to use them, trials moved to measure changes in the child's overall development, particularly their cognitive functioning and social skills.

Over the past 30 years, the negative impact of immobility or inefficient mobility in toddlers with physical impairments has been cast under the spotlight. For typically developing toddlers, the onset of self-produced locomotion has been recognized to induce positive changes in their developmental processes (Campos et al., 2000). Toddlers are observed to learn key skills through mobile play and exploration, but in the presence of physical impairment, the same need for learning these skills through mobility may be hindered. Conversely, children with physical limitations could instead be prone to a condition termed as 'learned helplessness',(Everland, 1984) where they learn, instead, to be resigned to accept their environment and to no longer seek to influence it.

"Children's mastery of functional mobility skills has been classified and categorized in several ways. Hays (1987) examined current existing diagnostic conditions of children without locomotion and divided them into four functional groups" (Wright-Ott, 2015, p.564).

1. *Children who will never ambulate.*
   This category includes children with cerebral palsy with severe involvement and spinal muscular atrophy types I and II. Generally, these children have no opportunity for independent mobility.
2. *Children with inefficient mobility who ambulate but are unable to do so at a reasonable rate of speed or with acceptable endurance.*
   This category includes children with cerebral palsy with less involvement and myelomeningocele with upper extremity involvement. For these children, assisted mobility may provide an efficient means of mobility above that which they are capable of producing themselves. Warren (1990) uses the term "marginal ambulator" for this group.
3. *Children who have lost their independent mobility.*
   This category includes victims of trauma and children with progressive neuromuscular disorders. The developmental implications may be less critical than in the first two groups, and the issue is acceptance of assisted mobility as an adaptation to an acquired disability,
4. *Children who temporarily require assisted mobility and often progress to independent mobility with age.*
   This category includes many children with osteogenesis imperfecta and arthrogryposis. Functional considerations in this group are both developmental and practical.

Children with mobility impairments, as categorized by Hays (1987) may benefit from the use of a power mobility device for functional mobility (Wright-Ott, 2015, p. 564) Regardless of the etiology, pathology or prognosis of the condition that limits mobility, children may be able to achieve increased functional mobility, even independent mobility if consideration to other factors are taken into account. These factors include but are not limited to "purpose and goals for the use of the device, environments for intended use, child's physical and psychosocial

abilities and limitations, modifications that may be needed for comfort and control, and cost-benefit ratio" (Wright-Ott, 2015, p. 564).

There are significant differences among these groups that may have implications for mobility and its integration into the child's overall concept of disability, as well as for evaluation and intervention. Group I children may achieve independent mobility through the use of a support walker or power wheelchair. Group II children may be able to independently propel a manual wheelchair, ambulate in a support walker indoors, and use a power wheelchair for community mobility. Children in group III and IV will use a variety of mobility methods during the transition period. (Wright-Ott, 2015, p.564).

"Introduction of Power Mobility Devices (PMD) for some therapists focuses on arbitrary age-based criteria while others look to a set of similarly arbitrary skills that indicate readiness. Researchers have been exploring how young children can begin using PMD. Typically developing infants aged between 5 and 10 months have been successful using a PMD that utilized whole body movement rather than a joystick (Larin, Dennis, & Stansfield, 2012). Researchers at University of Delaware have had success with infants with and without disabilities initiating movement using joysticks at 7 months (Lynch et al., 2009), 11months (Ragonesi & Galloway, 2012) and 14 months-of-age (Galloway et al., 2008). Case studies describe children with age-appropriate cognitive skills using PMD competently as young as 17 months (Zazula & Foulds, 1983), 20 months (Jones, McEwen, & Hansen, 2003), and 22 months-of-age (Everard, 1984). Jones et al (2012) showed that 14-30-month olds who had frequent access to a PMD in the home setting learned successful mobility skills in the presence of significant disability." (Rosen, Plummer, Sabet, Lange, & Livingstone, 2018, p.4). Many practitioners believe that provision of a PMD should be considered within the first year of life (Wright-Ott, 2015, p.563). However, current research suggests that children as young as 5-7 months of age are successful at operating a PMD. Infants, at six months of age begin to be mobile in their environment. Additionally, at 6 months of age an infant has a strong inner drive to reach to midline and engage in bilateral and unilateral reaching, grasping and manipulating objects (such as a joystick). They display adequate head and trunk extension to support themselves in an upright seated position (Parham & Mailloux, 2015, p. 263). "Growing evidence indicates that these early motor experiences not only inform children about their own actions, but also the action of others" (Woodward, 2009). For an infant unable to be independent in self-initiated mobility, the opportunity to explore their environment by accessing a midline-oriented device provides an inherently motivating means of control.

PMD for young children and toddlers has been evolving to provide an efficient option to assist mobile play and exploration; however, no PMD has been successfully marketed in large volumes before. The testing of the Explorer Mini is an innovative and unique mobility device that is well suited to provide an opportunity to assess an infant's readiness to utilize a supported seat and midline control device to demonstrate self-initiated mobility.

3 Purpose and Scope

The scope of the human factors validation test is to demonstrate that the device can be used safely by the intended users, for its intended use. The preliminary analyses, as described in the human factors validation plan, builds the rationale behind the device related tasks included in the test and it will be performed on a device and accompanied labelling that represent the final design.

The test will be performed in a clinical setting including participating children, their parents/guardians and physiotherapists/occupational therapists (PTs/OTs) at three clinical sites in the United States of America, post evaluation and approval from applicable Internal Institutional Review Board (IRB). A clinical setting, while not fully reflective of a home

environment is the typical testing area for mobility related assessments as trained practitioners (PTs/OTs) have access to a variety of devices, and a means of creating a safe environment specific to the child. The clinic is also the place where the child and parent/guardian in real world situation would be introduced to and trained on a mobility device.

4 Sample and recruitment

4.1 Eligibility criteria

The test participants represent the two populations of intended users:

Primary users – children with mobility impairments
Secondary users – care-givers (parents/guardians and PTs/OTs)

4.1.1 Inclusion criteria

Primary users:

- Informed consent signed by parents or guardian
- Aged 6-36 months
- Unable to mobilize independently for exploratory play and peer interaction, as cathegorized by Hays (1987)
- Adequate trunk and head control to remain upright in the device, including regain head control
- Adequate hand/ arm (distal) control to reach for objects in front of them

Evaluation of children has traditionally focused on achievement of developmental milestones. However, underlying impairments cannot fully explain the extent and form of functional difficulties seen in children with mobility impairments (Coster, 1998). Additionally, "the tasks most relevant for functional mobility have not been well defined in traditional developmental milestone test" (Wright-Ott, 2015, p. 564). In this test, all included children have a mobility impairment but for reasons described above, no specific diagnosis is set as inclusion criteria for the primary user and the mobility impairment of the user will depend on a variety of diseases, diagnoses, cognitive or functional disorders.

Secondary users:

- Signed informed consent
- PT/OT or parent/guardian of the child included in the test

4.1.2 Exclusion criteria

Primary users:

- Weight >16 kg/35 lbs
- Length >100 cm/39 In
- Children that lack head control in such a severe manner that they cannot regain control if it is lost
- Children who do not show awareness of or respond to toys, objects, sounds and/or people in their environment
- Any other reason, if in the opinion of the investigator, the individual user is not appropriate, or suitable for participation in the test.

Secondary users:

- Hearing/vision loss or limited cognitive skills impacting the ability to take instructions and perform the tasks of the test
- Ability to understand oral and written English as product labelling will in this HF validation test only be available in English
- Any other reason, if in the opinion of the investigator, the individual user is not appropriate, or suitable for participation in the test

4.2 Sampling

Because successful mastery of a power mobility device has been demonstrated with children over the age of 17 months, and children as young as 7 months demonstrate early skills necessary for power mobility the testing groups will be set at 6-17 months and 18-36 months. It is anticipated that children with supported trunk (proximal) control will have adequate hand/ arm (distal) control and inherent motivation and development to operate a midline-oriented control.

Enrollment of eligible children will be conducted to ensure 30 per protocol performed tests, 15 children per age group.

6 months – 17 months	15 children
18 months – 36 months	15 children

Along with the 30 children, their 30 parents/guardians will be actively participating in the study as well as their PT/OT.

4.3 Recruitment

Recruitment will be initiated after a favourable decision from the local IRB has been received. The study clinics will be participating in this test, recruiting 10 children/parent pairs each. The principal investigators will reach out to PTs/OTs, to identify children managed by them who would match the inclusion/exclusion criteria of this test. A recruitment script may be used (see attachment 4). It is expected that there is an established connection between the child and the PT/OT already prior to this test.

4.3.1 Informed consent

Informed consent will be obtained prior to the participants undergoing any activities that are specifically for the scope of the test. In the process of gaining informed consent, the child's parents/guardian and PT/OT will receive information about the nature and objectives of the study, possible risks associated with their participation, their free choice of participating and leaving at any time, both in writing and orally. They will also have the opportunity to ask questions and be able to retain the information long enough to make an effective decision.

5 Study design and conduct

This is a descriptive, cross-sectional study to evaluate users' interactions with and perceptions of the device user interface. This will be done in two major steps:

- Observations of users´ performance of all critical and some non-critical tasks identified in the preliminary analyses and evaluations (observational data)
- Debriefing interview to collect the users´ perspective of the device (interview data)

5.1 Methodology

The introduction of the device to the children and caregivers will, once the product is commercially available, be performed by a PT/OT. Supplemental instructions will be given in the user's manual. In order to validate that the device is safe to use also without having received any training, the first observational part of the study will be performed in three steps.

1. To simulate an initial encounter with the device for a PT/OT where the device may be handled without any additional instructions, the child's PT/OT will first perform the test tasks untrained. The PT/OT will be provided with the User's manual but may not be prompted to use it for written information of the product.

2. In standard of care, after having learned how to use the device, a PT/OT would show the parent/guardian how to operate the device. In step two, the Principal Investigator will train the parent/guardian and the PT/OT on the device (standard product training) supported by references to the Users' manual.

3. The parent/guardian performs the test tasks, supported with the Users' manual and PT/OT or Principal Investigator.

The Principal Investigator will provide arm's length supervision throughout all steps of the study to ensure the safety of all participants.

5.1.1 Screening and enrolment

After having obtained written informed consent from the participants the Principal Investigator will control and ensure that the inclusion and exclusion criteria of this study protocol are met (including weight and length measure), and complete the upper part of the child test form, attachment 3, covering background information on the child.

The enrolment can, but does not need to, be done on the same day as the actual test.

5.1.2 HF Validation test – Observations

1. The child's PT/OT is presented to the device and it's labelling and is asked to:
   - connect the battery charger to the battery charging port, and disconnect it.
   - adjust the seat and table height so that they are appropriate for the child.
   - adjust the speed of the device so that it is appropriate for the child.
   - place the child into the device.
   - if needed, adjust cushion and/or other support to ensure that the child is placed properly and safely.

   The PI documents the observations on an observation form, attachment 1.

2. The Principal Investigator presents the device and labelling (including user manual) to the parent/guardian and PT/OT and performs a standard product training of the device.

3. The parent/guardian is presented to the device and it's labelling and is asked to:
   - connect the battery charger to the battery charging port, and release it.
   - adjust the seat and table height so that they are appropriate for the child.
   - adjust the speed of the device so that it is appropriate for the child.
   - place the child into the device.
   - if needed, adjust cushion and/or other support to ensure that the child is placed properly and safely.

   The PI documents the observations on another observation form, attachment 1.

The activities above are derived from the risk-analysis of the device, performed prior to this test, and are performed by the secondary users, where the child is needed in order to perform them but does not play an active role.

One PT/OT may be the professional care-giver to more than one of the children included in the test. Step one above will only be performed once for an individual PT/OT.

4. As the child is placed in the device by the parent/guardian, the child is allowed to explore the device for 5 minutes. The child will be instructed to place their hand on the joystick and watch how he/she can move it. If the child does not initiate after a verbal prompt the Principal Investigator will place the child's hand on the joystick. The child test form, attachment 3, will be used to describe the child's actions and reactions.

   If the child seems interested they may be placed in the device up to two times during the visit, with at least five minutes of rest in between. If the child shows signs of distress (such as crying) for at least one-minute, then they will be taken out of the device for a five-minute rest period. A new attempt will be made to place the child in the device. A maximum of three, one-minute attempts will be made to provide an opportunity for the child to use the device before this step is ended.

The Principal Investigator will use the observation form for secondary users to document observed user problems and use errors during the test, see attachment 1.
The Principal Investigator will complete two forms per test:

1. The child's PT/OT (performing the test without training)
2. The child's parent/guardian (performing the test with training)

The Principal Investigator will use a child test form for primary users to document observed user problems and user errors during the test as well as the ability to get the device in motion and the child's actions and reactions.

User errors performed during the tasks will be divided into three severity levels:

1. User experienced difficulties in performing the task but did not lead to harm
2. User performed an error that could have resulted in harm but never did
3. User performed an error that resulted in harm.

Details of the risk analysis performed in the preliminary analysis can be found in the Human Factors validation plan ES1692.

5.1.3 HF Validation test – Interviews

After the tasks in 5.1.2 have been performed, the Principal Investigator will interview the child's parent/guardian and PT/OT, in order to collect their perspectives of the tasks, to complement the task performance observations. An interview form, attachment 2, will be used.

6 Reporting results

The test data will consist of:
1. Completed observation forms
2. Completed interview forms
3. Completed child test forms

6.1 Data analysis

After completion of the human factors validation testing, the results of the observations and interviews will be analyzed qualitatively and quantitatively to determine if the design of the

device can be used by the intended users without serious use errors or problems. The results will be summarized in a human factors validation report.

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8 Attachments

Attachment 1 Observation form
Observation form, HF validation test protocol 06 August 2018

Attachment 2 Interview form
Interview form, HF validation test protocol 06 August 2018

Attachment 3 Child test form
Child test form, HF validation test protocol 06 August 2018

Attachment 4, Recruitment script
Recruitment script, HF validation test protocol 06 August 2018