



# ISPO Scientific Committee

Recommendation for Defining Participants in Prosthetics Research

Edward Lemaire, Man-sang Wong – June 18, 2013

## Introduction

An understanding of research participant characteristics is essential for interpreting results in the scientific and consumer literature. In the field of prosthetics, these characteristics are often under-reported, or inconsistently presented, leaving the reader to make assumptions on the study design and clinical application of the results. Prosthetic studies require not only typical personal information, such as height, weight, and gender, but descriptions of the prosthetic components and other assistive devices.

For the researcher, the decision on participant information data collection is made during the study design phase, and is typically difficult or impossible to obtain after data collection is complete and the results are being disseminated. A participant information minimum data set would be used when planning prosthetic studies, to collect appropriate participant data during the participant encounters, and assist study reviewers by providing a set of criteria that could be adopted for publication assessment.

This document is a recommendation for an ISPO-sanctioned data set for reporting participant characteristics in prosthetic research and development publications. While this recommendation will have direct benefits for typical scientific publications, such as Prosthetics and Orthotics International, the data set can also improve how technical and clinical reports are designed and reported to the prosthetic community.

The data set includes a comprehensive list of items, descriptions, and formats for all possible descriptors. Researchers would typically not use the complete data set to describe study participants. A minimum data set is also presented and includes prosthetic descriptors that should be included in all publications.

## Overall Considerations

- Characteristics that apply to all participants should be mentioned in the manuscript text (e.g., all subjects were males with transtibial amputations, all prostheses used a PTB design with supracondylar suspension, etc.).
- The appropriate professional that reviewed the prosthesis and/or stump prior to inclusion in the study should be noted in the manuscript text (i.e., prosthetist [ISPO Category or certification], medical doctor, physical therapist, occupational therapist, prosthetic technician)
- A table with each participant's unique characteristics should be included
- For group data, report mean and standard deviation for quantitative measures
- Product year or version number can be included for prosthetic components to help define iterative product updates that can affect function

## Data Set – Lower Extremity

Item	Description	Format
<b>Personal Characteristics</b>		
Sex	Male or female	Male, female (count)
Age	Age at first data collection session	Years
Height	Height at first data collection session	Height (cm)
Weight	Weight at first data collection session	Weight (kg)
Amputation side	Limb side(s)	Left, right, bilateral
Amputation level	Amputation level for each amputated limb	ISO standard terminology for amputation level
Reason for amputation	Reason for the amputation	Trauma, vascular disease, cancer, congenital, other
Time since amputation	Time from amputation to first data collection session	Years
Prosthetic experience	Time using a prosthesis and/or time using the prosthesis evaluated in the research	Years
Stump shape	Shape categorization	Conical, bulbous, cylindrical, irregular
Stump sensation	Qualitative assessment of stump sensation	Normal, hypersensitive, protective sensation only, insensate, phantom pain.
Joint range of motion	Lower extremity joint motion categorization for affected side(s)	Normal, limited (contracture), hypermobile (hyperextension, etc.)
Residual limb strength	Manual muscle testing score or other measure	Reference the scale being used (Oxford-MRC, etc.). Typically 0-5 grading.
General health condition	Related to mobility (physical ability, cardiopulmonary function, balance, vision, mental status)	List of health issues related to mobility (can include outcome measures)
<b>Mobility Training and Devices</b>		
Therapist training	Has person received training from a physiotherapist or occupational therapist	Gait training, assistive device training, specialized training (running, etc.)
Assistive devices	Other assistive or mobility devices (cane, walker, orthoses, etc.)	List of non-prosthetic assistive devices
<b>Prosthesis Characteristics</b>		
Structural design	Exoskeleton or Endoskeleton	Material, brand name, manufacturer year, manufacturer version number
Socket type	Type of prosthetic socket (include inner and outer sockets if necessary)	ISO standard terminology for socket type
Suspension type	Type and products for socket suspension	Type or brand name, manufacturer year, manufacturer version number

Prosthetic foot	Type of prosthetic foot	Type or brand name, manufacturer year, manufacturer version number
Prosthetic ankle	Type of prosthetic ankle	Type or brand name, manufacturer year, manufacturer version number
Prosthetic shank	Type of prosthetic shank (pylon)	Type or brand name, manufacturer year, manufacturer version number
Prosthetic knee	Type of prosthetic knee	Type or brand name, manufacturer year, manufacturer version number
Prosthetic thigh	Type of prosthetic thigh (pylon)	Type or brand name, manufacturer year, manufacturer version number
Prosthetic hip	Type of prosthetic hip	Type or brand name, manufacturer year, manufacturer version number
Stump socks	Type of stump socks	Material, size, brand name, manufacturer year, manufacturer version number

## Minimum Data Set – Lower Extremity

Item	Description	Format
Sex	Male or female	Male, female (count)
Age	Age at first data collection session	Years
Weight	Weight at first data collection session	Weight (kg)
Amputation level	Amputation level for each amputated limb	ISO standard terminology for amputation level
Reason for amputation	Reason for the amputation	Trauma, vascular disease, cancer, congenital, other
Assistive devices	Other assistive or mobility devices (cane, walker, orthoses, etc.)	List of non-prosthetic assistive devices
Structural design	Exoskeleton or Endoskeleton	Material, brand name, manufacturer
Socket type	Type of prosthetic socket (include inner and outer sockets if necessary)	ISO standard terminology for socket type
Suspension type	Type and products for socket suspension	Type or brand name, manufacturer
Prosthetic foot	Type of prosthetic foot	Type or brand name, manufacturer
Prosthetic ankle	Type of prosthetic ankle	Type or brand name, manufacturer
Prosthetic shank	Type of prosthetic shank (pylon)	Type or brand name, manufacturer
Prosthetic knee	Type of prosthetic knee	Type or brand name, manufacturer
Prosthetic thigh	Type of prosthetic thigh (pylon)	Type or brand name, manufacturer
Prosthetic hip	Type of prosthetic hip	Type or brand name, manufacturer
Stump socks	Type of stump socks	Material or brand name

## Data Set - Upper Extremity

Item	Description	Format
<b>Personal Characteristics</b>		
Sex	Male or female	Male, female (count)
Age	Age at first data collection session	Years
Height	Height at first data collection session	Height (cm)
Weight	Weight at first data collection session	Weight (kg)
Amputation side	Limb side(s)	Left, right, bilateral, dominant side
Amputation level	Amputation level for each amputated limb	ISO standard terminology for amputation level
Reason for amputation	Reason for the amputation	Trauma, vascular disease, cancer, congenital, other
Time since amputation	Time from amputation to first data collection session	Years
Prosthetic experience	Time using a prosthesis and/or time using the prosthesis evaluated in the research	Years
Stump shape	Shape categorization	Conical, bulbous, cylindrical, irregular
Stump sensation	Qualitative assessment of stump sensation	Normal, hypersensitive, protective sensation only, insensate, phantom pain
Joint range of motion	Upper extremity joint motion: categorization for affected side(s) or angular range	Normal, limited (contraction), hypermobile (hyperextension, etc.)
Residual limb strength	Manual muscle testing score or other measure	0-5 grading
General health condition	Related to function (physical ability, vision, mental status)	List of health issues related to function (can include outcome measures)
<b>Training</b>		
Therapist training	Has person received training from an occupational therapist or physiotherapist	Functional training, physical training
<b>Prosthesis Characteristics</b>		
Design	Prosthetic device category	Body powered, myoelectric, cosmetic
Socket type	Type of prosthetic socket (include inner and outer sockets if necessary)	ISO standard terminology for socket type
Suspension type	Type and products for socket suspension	Type or brand name, manufacturer year, manufacturer version number

Prosthetic hand	Type of prosthetic hand	Type or brand name, manufacturer year, manufacturer version number
Prosthetic wrist	Type of prosthetic wrist	Type or brand name, manufacturer year, manufacturer version number
Prosthetic elbow	Type of prosthetic elbow	Type or brand name, manufacturer year, manufacturer version number
Prosthetic shoulder	Type of prosthetic shoulder	Type or brand name, manufacturer year, manufacturer version number
Prosthetic controller	Controller-specific details	Type or brand name, manufacturer year, manufacturer version number
Stump socks	Type of stump socks	Material, size, brand name, manufacturer year, manufacturer version number

## Minimum Data Set – Upper Extremity

Item	Description	Format
Sex	Male or female	Male, female (count)
Age	Age at first data collection session	Years
Amputation side	Limb side(s)	Left, right, bilateral, dominant side
Amputation level	Amputation level for each amputated limb	ISO standard terminology for amputation level
Reason for amputation	Reason for the amputation	Trauma, vascular disease, cancer, congenital, other
Design	Prosthetic device category	Body powered, myoelectric, cosmetic
Socket type	Type of prosthetic socket (include inner and outer sockets if necessary)	ISO standard terminology for socket type
Suspension type	Type and products for socket suspension	Type or brand name, manufacturer
Prosthetic hand	Type of prosthetic hand	Type or brand name, manufacturer
Prosthetic wrist	Type of prosthetic wrist	Type or brand name, manufacturer
Prosthetic elbow	Type of prosthetic elbow	Type or brand name, manufacturer
Prosthetic shoulder	Type of prosthetic shoulder	Type or brand name, manufacturer
Stump socks	Type of stump socks	Material or brand name

## Appendix A – Assessment Tools

This appendix outlines measures that can be included to describe participants in prosthetics research.

### Manual Muscle Testing

- Grade 5: Patient can hold the position against maximum resistance and through complete range of motion.
- Grade 4: Patient can hold the position against strong to moderate resistance, has full range of motion.
- Grade 3: Patient can tolerate no resistance but can perform the movement through the full range of motion.
- Grade 2: Patient has all or partial range of motion in the gravity eliminated position.
- Grade 1: The muscle/muscles can be palpated while the patient is performing the action in the gravity eliminated position.
- Grade 0: No contractile activity can be felt in the gravity eliminated position.

### Sensation

- Monofilament test: Monofilament type (10g, 4.5g, etc.), location of insensitive areas

### Other Biomechanical Measures

- Leg length discrepancy (m)
- Piston action (m)
- Walking speed (m/s)
- Steps taken (step/min)
- Socket interfacial pressure (kPa)
- Other kinematic and kinetic gait parameters