CEN

WORKSHOP

AGREEMENT

CWA 17664

April 2021

ICS 25.040.30

English version

Lower-limb wearable devices - Performance test method for walking on uneven terrain

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Ref. No.:CWA 17664:2021 E

Contents

European foreword

CWA 17664:2021 has been developed in accordance with the CEN-CENELEC Guide 29 “CEN/CENELEC Workshop Agreements – A rapid way to standardization” and with the relevant provisions of CEN/CENELEC Internal Regulations – Part 2. The proposal was approved and supported by CEN following a public call for participation made on 2020-05-25. The Kick-off Meeting took place on 2020-06-29 and the final CWA was approved by representatives of interested parties in a Workshop on 2021-03-17. It does not necessarily reflect the views of all stakeholders who may have an interest in its subject matter.

Results incorporated in this CEN Workshop Agreement received funding from the European Union’s Horizon 2020 research and innovation programme under the grant agreement numbers 779963 (EUROBENCH) and 780073 (INBOTS). The final text of CWA 17664:2021 was submitted to CEN for publication on 2021-03-26.

The following organisations and individuals developed and approved this CEN Workshop Agreement:

- Spanish National Research Council/ Diego Torricelli (Chairperson), Stefano Massardi, Adriana Belén Torres Pardo, David Pinto Fernandez;
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- Sejong University/ Gwak Kwan-Woong;
- SNCF Voyageurs/ Yonnel Giovanelli;
- Technaid S.L./ Javier Roa, Andrés Quesada;
- Tecnalia Research and Innovation/ Arantxa Renteria, Anthony Remazeilles;
- The Dalle Molle Institute for Artificial Intelligence/ Loris Roveda.

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Introduction

Human-centred wearable devices, such as prostheses and exoskeletons, are becoming increasingly relevant worldwide. Many prototypes are moving out of the lab into everyday applications, in a wide range of market domains. Several roadblocks exist in this process. Some of these are technical, while others are related to the lack of reliable test methods and performance indicators for these devices.

The *Strategic Research Agenda for Robotics in Europe* [1] has emphasized benchmarking as an important instrument to assess the Technology Readiness Level (TRL) and to quantify how robotic solutions match user needs. International efforts (e.g. RoboCup, European Robotics League, Cybathlon, DARPA Robotic Challenge) have confirmed the interest of the scientific and industrial communities in evaluating (and comparing) the performance of wearable devices and other types of robots in real-life environments. The *Multi Annual Roadmap for Robotics in Europe (MAR)* [2] has proposed a comprehensive list of system abilities to help quantifying the performance of a system. Nevertheless, due to the high variability of devices, applications and technologies, it is still not clear how system abilities can be quantified and measured on a realistic and application-specific basis.

This CEN Workshop Agreement provides means to obtain performance evaluation of lower-limb wearable devices during locomotion on uneven terrains. The recommended methodology needs further agreement in the scientific and industrial community to be converted into requirements.

This CEN Workshop Agreement has been prepared in cooperation of science and research institutes, small- and medium sized enterprises and larger manufacturers of lower-limb wearable devices. The draft CEN Workshop Agreement has been published for commenting on the CEN Website from 2020-12-01 to 2021-01-31.

The wearable devices to be tested with the CEN Workshop Agreement should be conform to relevant safety standards (e.g. EN 60601-1, EN ISO 13482, EN ISO 22523, EN ISO 10328, EN ISO 22675).

In this document, the following verbal forms are used:

- “shall” indicates a requirement,
- “should” indicates a recommendation,
- “may” indicates a permission,
- “can” indicates a possibility or capability.

1 Scope

This CEN Workshop Agreement defines a methodology to obtain performance indicators of lower-limb wearable devices during locomotion on uneven terrain, which enables a quantitative comparison of these performance indicators between systems.

This document includes:

- a morphological description of a test bed composed of different combinations of inclined uneven, stepped, soft and unstructured terrain,
- a set of required and recommended performance indicators,
- the experimental procedure needed to collect the performance indicators, and
- the structure of a unified test report.

This document is intended to be used by developers, manufacturers, researchers, and end-users of any type of lower-limb orthoses, exoskeleton or prostheses, independently from the structural properties (hard or soft), actuation typology (powered or unpowered), body coverage (trunk, spine, hip, knee, ankle, full leg), and application domain (industrial, healthcare, consumer).

Part of this document may be applied to other types of bipedal systems, e.g. humanoids, either autonomous or teleoperated. In these cases, this CWA represents a basis that may be extended by including other aspects specifically related to these bipedal systems (e.g. autonomy decision, perception, or cognitive abilities).

This document does not apply to non-bipedal over ground systems, e.g. wheeled robots, quadrupeds, and hexapods. It is out of the scope of this document to provide a scientific or clinical meaning to the proposed performance indicators. The interpretation of the results obtained from the application of this CWA is left to the user of the document.

The defined methodology is not suitable for comparing the performance of lower-limb orthopaedic devices in activities of daily living, although elements of the test bed appear to be similar to everyday obstacles.

As different users of orthopaedic devices show different conditions, the comparison of quantified performance indicators is only valid for the same subject. Performing activities of daily living similar to the described test is for example accompanied by sudden deflecting events like dual tasks, decreasing concentration and tiring. In contrast, the test bed provides repeatable constraints.

The comparisons obtainable by this test method refer to the performance of the entire bipedal system; in the orthopaedic field, that includes the individual embedding of the remaining body structure and several other components assembled in the orthopaedic device. This methodology does not support conclusions about the performance of single elements in the observed system.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardisation at the following addresses:

- IEC Electropedia: available at https://www.electropedia.org/

- ISO Online browsing platform: available at https://www.iso.org/obp

3.1
wearable device
mechanical or mechatronic device attached to the human body for supplementing and augmenting motor functions

Note 1 to entry: *Supplementing* means allowing the human to perform motor functions in a more efficient and/or effective way. *Augmenting* means allowing the human to perform motor functions above the average human strength.

3.2
orthosis
wearable device (3.1) working in parallel with the human body used to compensate for impairment of the structure and function of the neuro-muscular-skeletal system

[SOURCE: modified ISO 8549-1:2020, 3.1]

3.3
exoskeleton
multi-segment orthosis (3.2)

3.4
prosthesis
wearable device (3.1) working in series with the human body, replacing or substituting for an anatomical part or deficiency

[SOURCE: modified ISO 7198:2016, 3.27]

3.5
uneven terrain
surface that is not level or smooth

3.6
measured variable
variable gained from sensors without any post-processing

3.7
performance indicator
post-processed measured variable (3.6) that supports the evaluation of an aspect of performance

[SOURCE: modified ISO/TR 22221:2006, 2.13]

3.8
observation
quantitative or qualitative information relevant for the contextualisation of the test result that is not considered a performance indicator (3.7)

3.9
self-selected normal speed
subject's preferred walking speed under the protocol condition

3.10
self-selected low speed
subject's preferred walking speed substantially slower than self-selected normal speed (3.9) under the protocol condition

3.11
self-selected high speed
subject's preferred walking speed substantially faster than self-selected normal speed (3.9) under the protocol condition

3.12
trial
single instance of a task carried out under identical conditions that can be repeated multiple times

[SOURCE: modified IEC 62929:2014, 3.11]

3.13
test
a collection of trials (3.12)

3.14
test supervisor
person responsible for overseeing the test, calculating the performance indicators, including observations and adding the test results to the test report form

3.15
test technician
person responsible for executing the test protocol and collecting the data of the trials

3.16
subject
person whose activity is measured during the test

3.17
test bed
piece of equipment reproducing the terrain on which the subject (3.16) has to move

4 Abbreviations

BoS	Base of support
BMoS	Backwards margin of stability
GDI	Gait deviation index
GLW	Ground level walking
ID	Identification
MLMoS	Mediolateral margin of stability
PI	Performance indicator
SHS	Self-selected high speed
SLS	Self-selected low speed
SNS	Self-selected normal speed

TRL Technological readiness level

XCoM Extrapolated center of mass position

5 Test bed

5.1 General

The test bed shall consist of a basic structure composed of a sloped surface with variable angles, and a horizontal surface that permits the subject to turn around and return to the initial position (see Figure 1). Different removable modules shall be attached onto this structure that reproduce uneven terrain. Handle bars shall be attached to both sides covering the entire length of the basic structure.

The dimension of the basic structure is as follows:

- width: minimum 1000 mm,
- length of the sloped surface walkway: minimum 3000 mm,
- length of the horizontal surface walkway: minimum 1000 mm,
- length of the flat run-up: minimum 3000 mm,
- slope range (variable height): 0º to 15º.

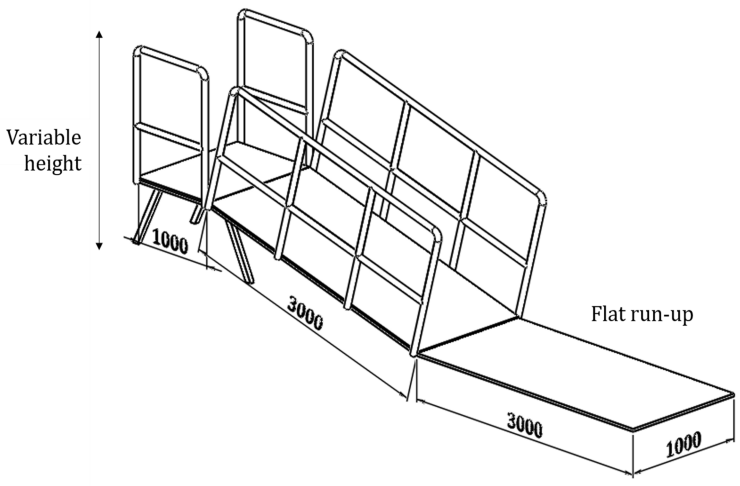

Figure 1 — Basic structure (dimensions are in mm)

5.2 Inclined uneven terrain

Twelve 500 mm x 500 mm modules of three different inclinations (5º, 10º, 15º) (see Figure 2) should be placed in different configurations on the basic structure over the 1000 mm x 3000 mm surface. It is not mandatory to implement all three different inclinations. Each module is recommended to be made of an anti-slip 500 mm x 500 mm wooden board of 18 mm thickness, three wedges of 5º, 10º or 15º, and four circular pegs, to allow the insertion of the module into the surface (plug-in system). The perforation of the surface board to which the modules are attached shall have a tolerance less than 1 mm to minimise motion when stepped over, as well as to ensure good fit when the module is rotated 90º.

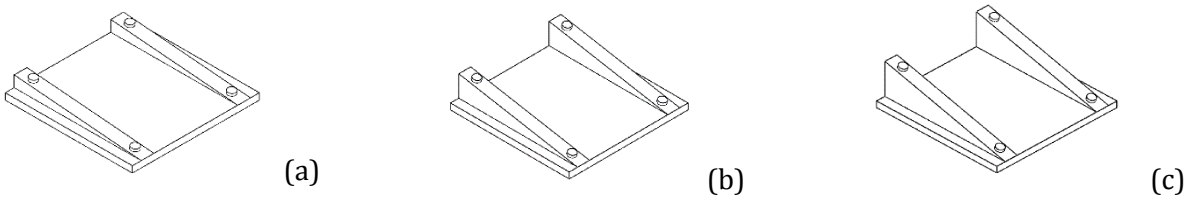

Figure 2 — Inclined modules of 5º (a), 10º (b) and 15º (c) inclination

The following inclined uneven terrain configurations should be used.

“A-like” inclined uneven terrain configuration

The modules are placed with lateral inclination, with the highest side at the centre of the walkway, creating a ridge in the middle of it (see Figure 3). The configuration should be abbreviated as followed:

- A5 (“A-like” configuration with a 5° inclination),
- A10 (“A-like” configuration with a 10° inclination),
- A15 (“A-like” configuration with a 15° inclination).

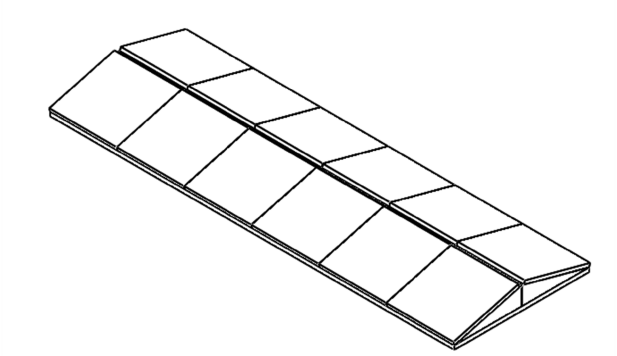

Figure 3 — “A-like” inclined uneven terrain configuration

“V-like” inclined uneven terrain configuration

The modules are placed with lateral inclination, with the highest side at the edges of the walkway, creating a depression in the centre (see Figure 4). The configuration should be abbreviated as followed:

- V5 (“V-like” configuration with a 5° inclination),
- V10 (“V-like” configuration with a 10° inclination),
- V15 (“V-like” configuration with a 15° inclination).

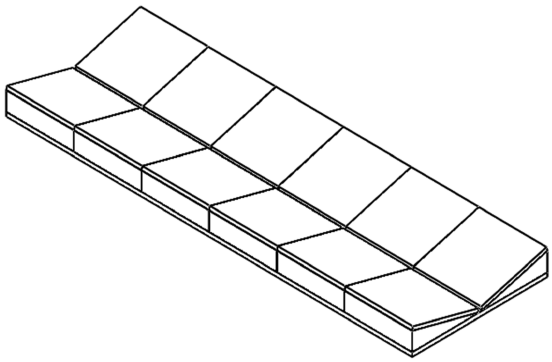

Figure 4 —"V-like" inclined uneven terrain configuration

"M-like" inclined uneven terrain configuration

The modules are placed sequentially with opposing inclinations in the direction of the walkway, creating an alternating up-down pattern (see Figure 5). The configuration should be abbreviated as followed:

- M5 ("M-like" configuration with a 5° inclination),
- M10 ("M-like" configuration with a 10° inclination),
- M15 ("M-like" configuration with a 15° inclination).

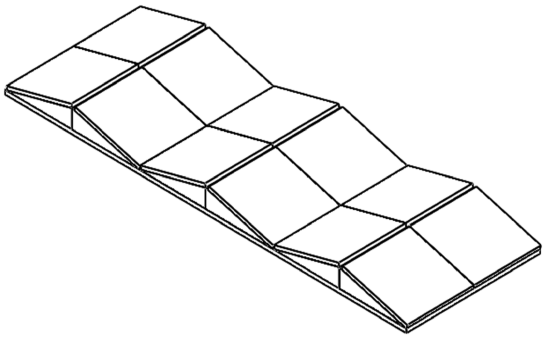

Figure 5 — "M-like" inclined uneven terrain configuration

5.3 Stepped terrain

This configuration combines four different heights to simulate steps of 22, 44, 66 and 88 mm (see Figure 6). Each module is recommended to be made of an anti-slip 500 mm x 500 mm wooden board of 18 mm thickness, a strip of 22, 44, 66 or 88 mm, and four circular pegs, to allow the insertion of the module into the surface (plug-in system). The perforation of the surface board to which the modules are attached shall have a tolerance less than 1 mm to minimise motion when stepped over, as well as to ensure good fit when the module is rotated 90º.

This configuration is designed to make the subject go up and down through each step height without the up step and down step being of the same height in consecutive order.

The configuration should be abbreviated as STEP.

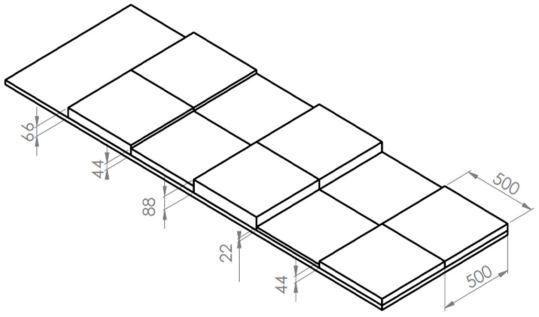

Figure 6 — Stepped terrain configuration (dimensions are in mm)

5.4 Soft terrain

Two mats with different densities and heights are recommended to be used (see Figure 7).

Soft-100 configuration

A density of 100 kg/m^3 and a height of 50 mm allows having a soft, yet reasonably stable surface.

The configuration should be abbreviated as SOFT100.

Soft-30 configuration

A density of 30 kg/m^3 and a height of 70 mm allows the feet to sink considerably into the material, without touching the supporting base.

The configuration should be abbreviated as SOFT30.

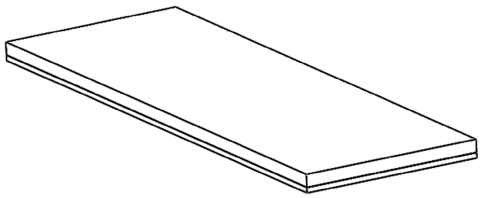

Figure 7 — Soft terrain configuration

5.5 Unstructured terrain

The configuration shall replicate a natural terrain whose surface curvature is continuously changing following an unpredictable pattern (see Figure 8 to Figure 10). The surface should be composed of a grid of 500 mm x 500 mm modules in which each module shall meet the following requirements:

- easily replicable with relatively little effort and a corresponding quality,
- materials for building each module are effortlessly accessible and shall be documented,
- maximum (peak-to-peak) vertical excursion of the surface within the module less than 500 mm,
- flat areas shall be smaller than 220 mm by 70 mm to ensure that the subject's feet/shoes are larger than the flat areas (see Figure 9),
- X-direction height gradient different from Y-direction height gradient,
- stiffness and friction of the module material shall be safe for the subject.

The configuration should be abbreviated as UNSTRUCTURED.

Three examples of possible unstructured terrain conditions are illustrated below.

Example 1: Floor foam panels like Terrasensa® can be used. Terrasensa® is a Sensa® product by the Hübner Group. This information serves only to inform the users of this CWA and does not mean that this product or company is recognised by CEN.

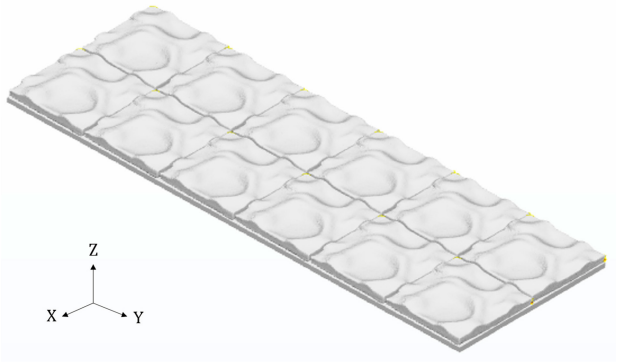

Figure 8 — Example 1

Example 2: Modules of 500 mm x 500 mm with a corrugated surface that are placed transversely, longitudinally and at 45º.

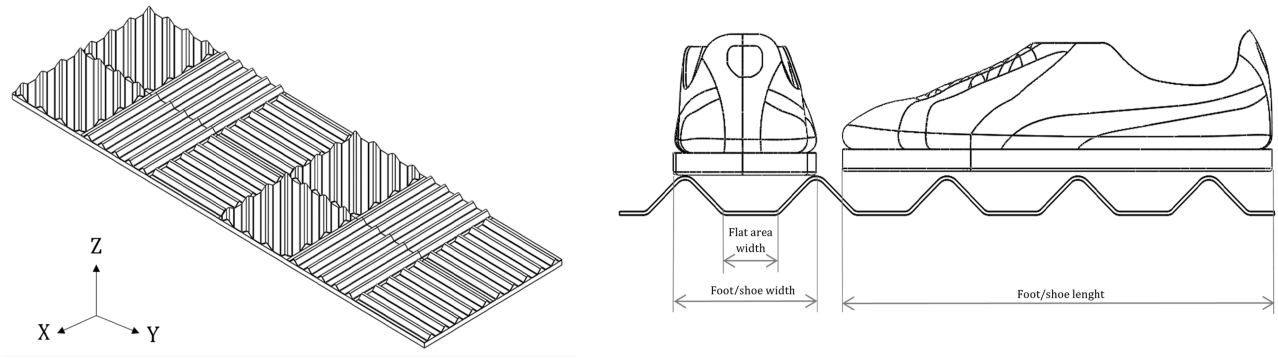

Figure 9 — Example 2

Example 3: Modules of 500 mm x 500 mm with a surface that has a pattern of semi-spheres of different diameters.

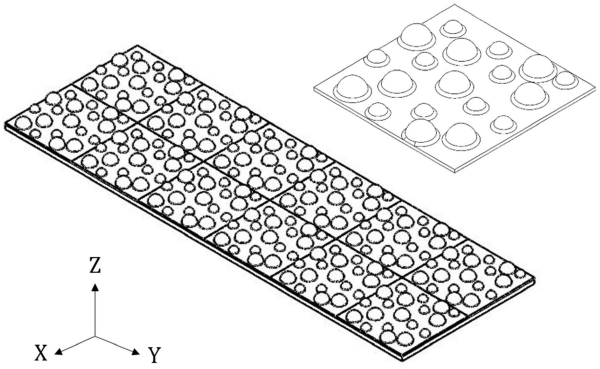

Figure 10 — Example 3

6 Performance indicators

6.1 Required performance indicators

The performance indicators (PIs) in Table 1 shall be calculated every time the subject goes through the test bed. This set of basic indicators can be obtained by most commercially available 3D motion capture systems.

The flat run-up is excluded from any calculation of the PIs.

Table 1 — Required performance indicators

No	Performance indicator	Description	ID
PI1	Time to complete	The time that is needed to complete the trial. Measured in: s.	TIME
PI2	Walking speed	The average walking speed of the subject during completion of the trial. This is calculated by dividing the length of the test bed by the total duration needed to complete the trial. Measured in: m/s.	SPEED
PI3	Cadence	The number of steps the subject makes per minute. Measured in: steps/min.	CADENCE
PI4	Stride duration	The time from initial contact of the considered leg until the subsequent initial contact of the same. Measured in: s.	STRIDETIME
PI5	Stance phase duration	Period of time in which the considered leg has contact with the surface. Measured in: s [or] % of stride duration.	STANCETIME
PI6	Swing phase duration	Period of time in which the considered leg has no contact with the surface. Measured in: s [or] % of stride duration.	SWINGTIME
PI7	1st double support phase duration	Period of time that starts with the initial contact of the considered leg with the terrain and ends with lifting of the foot of the contralateral leg from the terrain. During this phase, the weight shifts from the contralateral leg to the considered leg. Measured in: s [or] % of stride duration.	DBSUPPORT1
PI8	Single support phase duration	Period of time that starts with the lifting of the foot of the contralateral leg and ends with initial contact of the contralateral leg. During this phase, the full bodyweight is placed on the considered leg. Measured in: s [or] % of stride duration.	SINGLESTANCE

PI9	2nd double support phase duration	Period of time that starts with the initial contact of the contralateral leg and ends with the lifting of the foot of the considered leg. During this phase, the weight is shifted from the considered leg to the contralateral leg. Measured in: s [or] % of stride duration.	DBSUPPORT2

6.2 Required observations

The observations in Table 2 are required to be recorded every time the subject goes through the test bed. An observation is a measurement taken by the test supervisor without a measurement system. This might not describe the performance, but can be useful for contextualising the test results.

Table 2 — Required observations

No	Observation	Description	ID
O1	Number of handrail touches	The number of times the subject touches the handrail during completion of the trial. In case a subject uses the handrail continuously, this observation shall be quantified as the total duration of continuous contact. Measured in: integer number [or] seconds.	HANDTOUCH
O2	Number of hesitations	The number of times the velocity of motion is substantially decreased within a trial. This can be reflected in a sudden change in one of the described PIs, such as a sudden shorter step length (see Table 3). Measured in: integer number.	HESITATE
O3	Successful execution	Whether the subject has completed the trial. Measured in: binary (0=failed, 1=succeeded).	SUCCESS
O4	Number of stumbles	The number of balance perturbations that occur during the completion of the trial. Balance perturbations can be detected either by visual inspection or by measuring alterations in the kinematics or kinetics. Measured in: integer number.	STUMBLE

6.3 Recommended performance indicators

The following PIs are recommended to be calculated (see Table 3). These indicators might be more difficult to calculate because they require the use of more complex motion capture systems and algorithms.

EXAMPLE A stereophotogrammetric system.

Table 3 — Recommended performance indicators

No	Performance indicator	Description	ID
PI10-Rec	Step length	Anteroposterior distance between the heel of the considered leg at initial contact and the heel of the contralateral leg. Measured in: m.	STEPLENGTH
PI11-Rec	Stride length	Anteroposterior distance between the heel of the considered leg at subsequent initial contacts. Measured in: m.	STRIDELENGTH
PI12-Rec	Step width	Medio lateral distance between the lateral side of the considered foot and the lateral side of the contralateral foot. Measured in: m.	STEPWIDTH
PI13-Rec	Variation of forward velocity	Interquartile range of the instantaneous forward velocity within a trial. It provides an indication on how fluently the subject is advancing. Hesitations, stumbles or sudden stops would be reflected in higher values of this PI. Measured in: m/s.	SPEEDVAR
PI14-Rec	Gait deviation index	The GDI, initially conceived to evaluate the gait of children with cerebral palsy [3], has been used as a quantitative parameter of gait pattern changes of individuals with other conditions [4, 5]. The GDI quantifies gait motion with a single parameter based on a kinematic data set [3]. It is defined as the scaled distance between 15 gait feature scores for a subject and the average of the same 15 gait feature scores for a control group. A GDI of 100 or higher indicates absence of abnormal gait patterns. If the GDI is lower than 100, each 10 points corresponds to a standard deviation away from the control group mean.	GDI
PI15-Rec	Walk ratio	The walk ratio is defined as the division of step length by cadence. It is speed independent and reflects energy expenditure, balance, between-step variability, and attentional demand. In healthy adults, its normal value is around 6.5 mm/ (step/min) [6]. Measured in: mm/ (step/min).	WALKRATIO

PI16-Rec	Ratio index	The ratio index is used to quantify gait symmetry. It is defined as the division of a gait parameter by the same gait parameter of the contralateral leg. Perfect symmetry is achieved when this parameter equals one. Higher or lower values indicate gait asymmetry [7]. Measured in: adimensional.	RATIOINDEX
PI17-Rec	Margins of stability	The margin of stability is a measure of stability during dynamic walking. Walking is defined stable, if the position of the extrapolated center of mass position (XcoM) is within the base of support (BoS). $XCoM = P_{CoM} + \frac{V_{CoM}}{\sqrt{g / l}}$ where *PCoM* is the vertical projection of the center of mass, *VCoM* is the velocity of the center of mass, *g* is the acceleration of gravity, *l* is the leg length. The margin of stability should be expressed using the backwards margin of stability (BMoS) and the mediolateral margin of stability (MLMoS). The BMoS is defined as the minimal distance between the XCoM and the BoS in the anteroposterior direction during the stance phase. The MLMoS is defined as the minimal distance between the XCoM and the BoS in the mediolateral direction during the stance phase. $BMoS = min_{stance}\ (XCoM_x - BOS_x)$ $MLMoS = min_{stance}\ (XCoM_y - BOS_y)$ where min_{stance} is the minimal distance during the stance phase, *XCoM* is the extrapolated center of mass position, *x* is the anteroposterior direction, *BoS* is the base of support, *y* is the mediolateral direction. Measured in: m	BMOS MLMOS

7 Test procedure

7.1 Test conditions

The test shall be conducted at self-selected normal speed (SNS) on at least one uneven terrain configuration, among those specified in Clause 5. For each uneven terrain configuration, it is required to perform the test with and without the wearable device (see Table 4).

The execution of the following two test conditions is required:

- Ground level walking (GLW) with the wearable device,
- Ground level walking (GLW) without the wearable device.

Tests are recommended to be conducted also at the following two speed conditions:

- Self-selected low speed (SLS),
- Self-selected high speed (SHS).

In the context of this document, “without wearable device” means the following:

- If the wearable device is an orthosis, then the subject is not wearing any orthosis. If the subject is not able to perform the test without the orthosis, this condition is not necessary.
- If the wearable device is a prosthesis, then the subject is wearing his/her own prosthesis.

Table 4 — Overview of test conditions

Test condition		Requirement	Recommendation
Self-selected normal speed (SNS)		X	
Self-selected low speed (SLS)			X
Self-selected high speed (SHS)			X
Uneven terrain configuration	Inclined uneven terrain (A5, A10, A15, V5, V10, V15, M5, M10, M15)	One configuration shall be selected.	X
	Stepped terrain (STEP)		X
	Soft terrain (SOFT30, SOFT100)		X
	Unstructured terrain (UNSTRUCTURED)		X
GLW with the wearable device		X	
GLW without the wearable device		X*	
Uneven terrain with wearable device		X	
Uneven terrain without wearable device		X*	
* If the subject is not able to perform the test without the wearable device this test condition is not applicable.			

7.2 Protocol

The protocol consists of a test with multiple trials. The subject should repeat the trial until reaching 10 strides at each uneven terrain configuration defined in the test report, in order to obtain statistically relevant data. The protocol shall be split-up into a *preparation* and *testing phase*.

Preparation phase

It is mandatory to have an *enrolment session* where the test technician explains the testing phase to the subject and collects the subject's data for the test report (see Clause 8). The protocol conditions shall be set in the preparation phase and shall be documented in the test report (see Clause 8).

After the *enrolment session*, it is mandatory to have a *familiarisation session*.

The subject shall conduct the following three familiarisation activities prior to the testing phase. All three activities shall have a duration greater than the "time of device familiarisation of the subject", defined in the test report (see Clause 8).

1. Familiarisation with the test bed: The subject shall walk without the wearable device on the test bed across the different uneven terrain configurations specified in the test report under protocol conditions.

2. Familiarisation with the wearable device: The subject shall walk with the wearable device over flat ground (Ground Level Walking (GLW) with the wearable device).

3. Familiarisation with the wearable device and the test bed: The subject shall walk with the wearable device on the test bed across the different uneven terrain configurations specified in the test report under protocol conditions.

It is recommended to have the preparation phase at least one day before the testing phase.

Testing phase

The testing phase shall be carried out after the preparation phase.

The testing phase consists of the following steps:

1. The test technician shall apply the subject with the selected measurement system. The measurement system shall allow the calculation of the required performance indicators (PIs) and should allow the calculation of the recommended PIs provided in Clause 6.

2. The subject shall perform a trial on ground level walking at self-selected normal speed (SNS) without the wearable device.

3. The test technician shall set up the uneven terrain configuration of the test bed according to the list of uneven terrain configurations specified in the protocol conditions of the test report. The test supervisor shall ensure that the chronological sequence of the terrain setup specified in the test report is followed.

4. The subject shall walk through the test bed at SNS without the wearable device. The test technician shall specify the testing condition data in the test report (see Clause 8). The trial at SNS shall be performed first, in order to provide a reference value of the PIs for the subject for the following trials.

5. Step 4 shall be repeated at SNS and, when considered, at self-selected low speed (SLS) and self-selected high speed (SHS). It is recommended to randomize the speed conditions by alternating SNS, SLS and SHS to avoid bias. The test supervisor shall ensure that the protocol conditions specified in the test report are followed.

6. The subject shall rest for the "standard time of the subjects' rest" defined in the protocol conditions of the test report (see Clause 8).

7. The test technician, test supervisor and subject shall repeat the protocol steps 3 to 7 for all uneven terrain configurations defined in in the protocol conditions of the test report.

8. The subject shall don the wearable device, with the help of the test technician if needed.

9. The test technician shall repeat the protocol steps 1 to 7. These steps will correspond to the "with the wearable device" test condition.

10. The test technician shall support the doffing of the wearable device and measurement system from the subject.

11. The test supervisor and the test technician analyse the acquired data and shall calculate, at least, the required PIs.

8 Test report

The test report shall collect all the data needed to replicate the test procedure (see Clause 7). The test report shall be filled out by the test technician for each subject. The calculated performance indicators, including observations, shall be added to the test report by the test supervisor.

Subject data

The following data shall be collected during the *enrolment session*:

- anthropometric data,
- clinical conditions (e.g. health status, neurological disorders, amputations),
- residual abilities (e.g. mental and physical assessment),
- ethical data (e.g. declaration of consent, data protection agreement).

The test technician shall follow ethical procedures and procedures for protection of personal data as required by (inter)national law.

Additional information regarding the subject's condition can be added.

Protocol conditions

The following data shall be defined during the *enrolment session*:

- test execution order,
- list of uneven terrain conditions,
- standard time of the subjects' rest,
- time of device familiarisation of the subject,
- number of trials,
- prior experience of the subject with the device (Yes/No),
- measurement system description,
- wearable device description (e.g. type of device, assistance level, control strategy).

Additional information regarding the protocol can be added.

Trial conditions

The trial conditions shall be reported every time the subject carries out a trial:

- speed condition (SNS, SLS, SHS),
- wearable device condition (with or without),
- terrain configuration (GLW/uneven terrain),
- wearable device configuration (e.g. level of assistance used, algorithms adopted).

The Annex provides a test report example.

Additional information regarding the trial condition can be added. ASTM F3427-20 can be taken into consideration, when documenting environmental conditions [8].

Recommendations for data files

The following good practices are recommended when reporting data:

- use of open source data-formats,
- self-explanatory labelling of data,
- organisation of files in a hierarchical structure,
- synchronisation of files among different measurement systems and timestamped files,
- provision of a data description and a list of variables.

The PI obtained in each trial should be identified according to the identification codes shown in Table 5.

Table 5 —Identification codes

ID	Description
SUBJECT	Descriptor of the subject with prefix “#”, e.g. #18.
PI-ID	ID of the PI, e.g. “STEPLENGTH” (see Table 1, Table 2, Table 3).
MODULES	Indication which configuration of the 500 mm x 500 mm modules is adopted. It is composed by the orientation ID (e.g. “A”, “V”, “M”) followed by the inclination of the modules (“5”, “10”, “15”), e.g. “A15” (see Subclause 5.2 to 5.5).
SURFACE	Material of the surface touched by the foot, to be chosen among the following IDs: “HARD”, “SOFT30”, “SOFT100”, “UNSTRUCTURED” (see Subclause 7.1).
DEVICE	Indication whether the subject was wearing the device or not. The possible IDs are “WITH” or “WITHOUT” (see Subclause 7.1).
SPEED	Indication of the type of selected speed. The possible IDs are “SNS”, “SLS”, or “SHS” (see Subclause 7.1).
REPETITION	The ID should include the word “REP” followed by the corresponding cardinal number.
SIDE	This ID indicates the side of the body the PI is referring to (LEFT or RIGHT). It is optional, because some of the PI are not referring to a body side.

An example of a concatenated identification code (and its value) is provided in the following string:

#18_ STEPLENGTH_A15_SOFT30_WITH_SNS_REP1.

NOTE The IDs are designed in a way that the identification string is univocally determined independently from the order of the IDs. Should one ID not be applicable, it can be left blank.

Annex A
Test report example

Annex A provides an example result reporting, based on data collected in real scenarios in all uneven terrain configurations without using a wearable device.

Table A.1, Table A.2 and Table A.3 show the test report as described in Clause 8.

Figure A.1 displays an example of result visualisation for PI2 (Walking speed).

Figure A.2 shows the required PIs (see Table 1) obtained from the experiment on uneven terrain configuration M15, with and without the device. The data from without the device do not correspond to real data.

Figure A.3 displays the required PIs obtained from one subject across three different uneven terrain configurations (GLW without the wearable device, M15 and STEP).

Table A.1 — Example form for subject data

Subject data			
Subject ID	#01		
Age	25	Gender	Female
Height [mm]	1800	Weight [kg]	75
Clinical condition	Healthy subject		
Residual abilities	Not applicable		
Ethical consent	Ethical approval number XX has been received.		
Anthropometric data for the selected PIs			
Right		*Left*	
Leg length [mm]	955	Leg length [mm]	960
Knee width [mm]	105	Knee width [mm]	100
Ankle width [mm]	75	Ankle width [mm]	78
Shoulder offset [mm]	32	Shoulder offset [mm]	34
Elbow width [mm]	70	Elbow width [mm]	75
Wrist width [mm]	40	Wrist width [mm]	40

Table A.2 — Example form for protocol conditions

Protocol conditions			
Device description	Bilateral 6dof-powered exoskeleton for rehabilitation use		
Time of device familiarisation of the subject	10 minutes	Prior experience of the subject with the device	Yes (expert user)
Standard time of subject's rest	5 minutes		
Number of trials	14		
Measurement system			
Sensor 1	Motion Capture System		
Manufacturer	VICON	Model	Vero 2.2
Resolution	2048x1048 MP	Sampling rate	100 samples/s
Data extracted	Angles, Angular velocities, Angular accelerations, Time		
Comments	A modified version of the VICON plug-in-gait model has been used.		
NOTE Additional information regarding the protocol can be added.			

Table A.3 — Example form for trial conditions

Trial conditions			
Trial n°	Speed condition (SNS, SLS, SHS)	Wearable device condition (with or without)	**Terrain configuration (GLW/uneven terrain)**
#1	SNS	Without	V5
#2	SNS	Without	UNSTRUCTURED
#3	SNS	Without	SOFT100
#4	SNS	Without	M5
#5	SNS	Without	A5
#6	SNS	Without	A10
#7	SNS	Without	SOFT30
#8	SNS	Without	GLW
#9	SNS	Without	V10
#10	SNS	Without	A15
#11	SNS	Without	V15
#12	SNS	Without	M15
#13	SNS	Without	A10
#14	SNS	Without	STEP

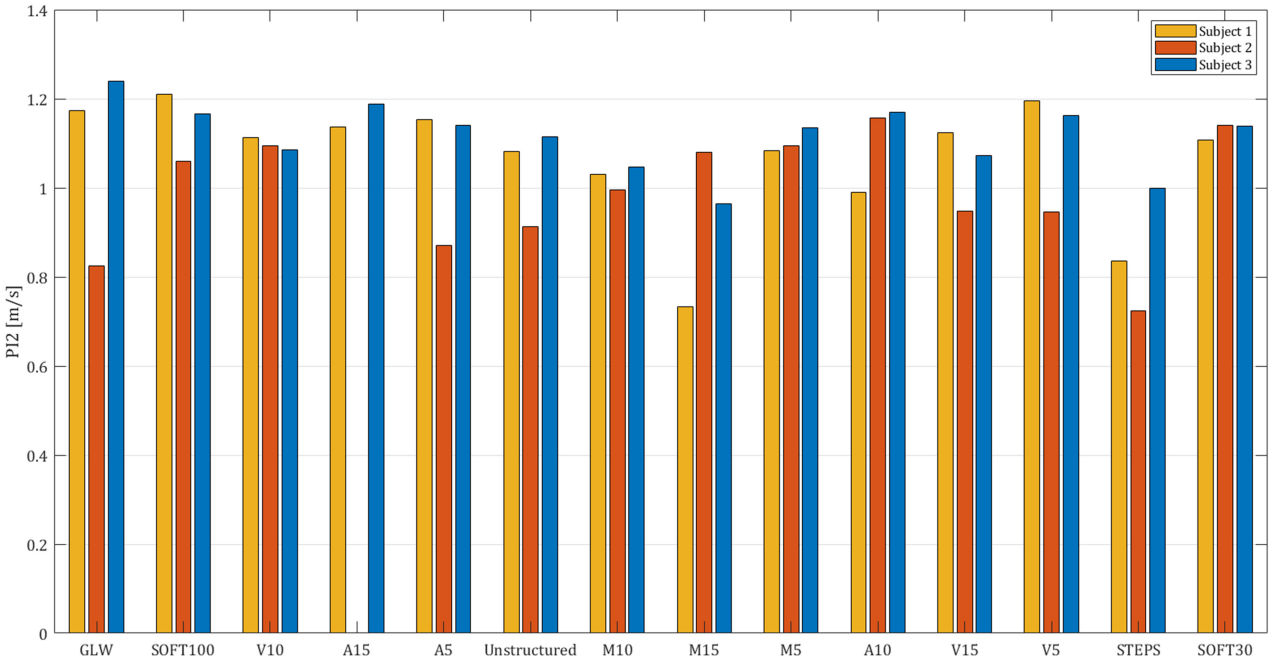

Figure A.1 — Example plot of PI2 in the uneven terrain configurations

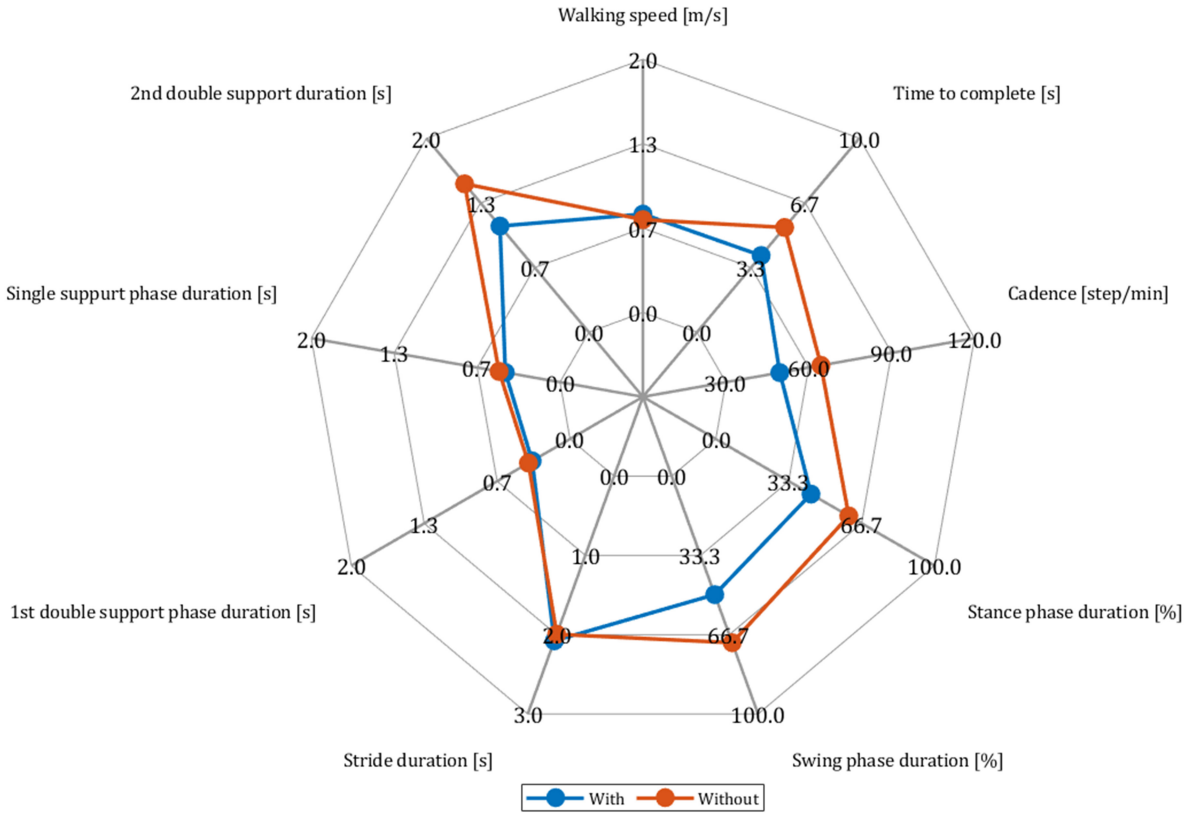

Figure A.2 — Example plot of required PIs in the uneven terrain configuration M15

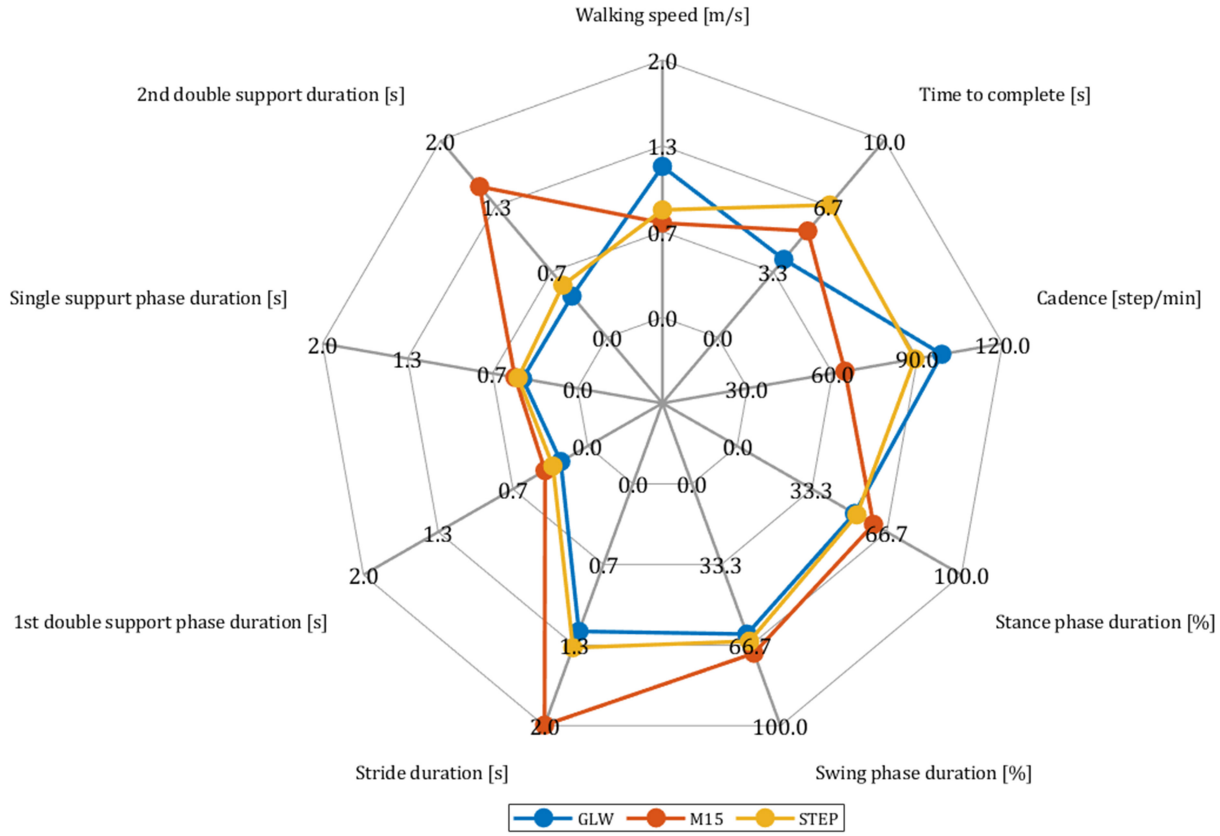

Figure A.3 — Example plot of required PIs for one subject in different uneven terrain configurations

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