CEN/WS 110

Date: 2020 -11

CWA XXXXX:2021

Secretariat: DIN

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

Tragbare Geräte für die unteren Extremitäten – Leistungstestmethode für das Gehen in unebenem Gelände

Dispositifs portables pour les membres inférieurs – Méthode de test de performance de la marche sur terrains accidentés

ICS: 25.040.30

Contents

European foreword

CWA XXXXX was developed in accordance with CEN-CENELEC Guide 29 'CEN/CENELEC Workshop Agreements – The way to rapid agreement' and with the relevant provision of CEN/CENELEC Internal Regulations – Part 2. It was agreed on 2020-06-29 in a Workshop by representatives of interested parties, approved and supported by CEN following a public call for participation made on 2020-05-25. It does not necessarily reflect the views of all stakeholders that might 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 XXXXX was submitted to CEN for publication on YYYY-MM-DD.

It was developed and approved by:

- Organization/ Workshop Member Name;
- ….

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1 Scope

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

This document includes:

- a morphological description of a test bed composed of different combinations of inclined uneven step, 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).

This document may be applied to other types of bipedal systems, including humanoids, autonomous or teleoperated robots. 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 relevant scientific communities.

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

3.1

wearable device

mechanical or mechatronic device attached to the human body for assisting, enabling, or augmenting motor functions

Note 1 to entry: *Enabling* means allowing the human to perform motor functions that could not be performed otherwise. *Assisting* 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

exoskeleton

multi-segment wearable device working in parallel with the human body

3.3

prosthesis

wearable device working in series with the human body, replacing or substituting for an anatomical part or deficiency

[SOURCE: modified ISO 7198:2016-08, 3.27]

3.4

uneven terrain

surface that is not level or smooth

3.5

performance indicator

post-processed measured variables that support the evaluation of an aspect of performance

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

3.6

measured variable

variable gained from sensors without any post-processing

3.7

observation

quantitative or qualitative information relevant for the contextualisation of the test result that is not considered a performance indicator

3.8

self-selected normal speed

subject's preferred walking speed under the protocol condition

3.9

self-selected low speed

subject's preferred walking speed substantially slower than self-selected normal speed under the protocol condition

3.10

self-selected high speed

subject's preferred walking speed substantially faster than self-selected normal speed under the protocol condition

3.11

trial

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

[SOURCE: modified IEC 62929:2014-07, 3.11]

3.12
test
a collection of trials

3.13
test supervisor
person responsible for setting up the apparatus, instrumentation, directing, and reporting results of the test

[SOURCE: modified ASTM F3323-20 Standard Terminology for Exoskeletons and Exosuits]

3.14
test technician
person responsible for executing the test protocol

[SOURCE: modified ASTM F3323-20 Standard Terminology for Exoskeletons and Exosuits]

3.15
test bed
piece of equipment reproducing the terrain on which the subject has to move

3.16
subject
person whose activity is measured during the test

4 Abbreviations

- BoS: Base of support
- COM: Center of mass
- GDI: Gait deviation index
- GLW: Ground level walking
- ID: Identification
- MoS: Margin of stability
- SHS: Self-selected high speed
- SLS: Self-selected low speed
- SNS: Self-selected normal speed
- XcoM: Extrapolated center of mass position

5 Test bed

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 should be attached onto this structure that reproduces uneven terrain. Handle bars shall be attached to both sides covering the entire length of the structure.

The recommended dimension of the basic structure is as follows:

- Width: minimum 1000 mm.
- Length of the sloped surface: minimum 3000 mm.
- Length of the horizontal surface: minimum 1000 mm.
- Slope range: 0º to 15º.

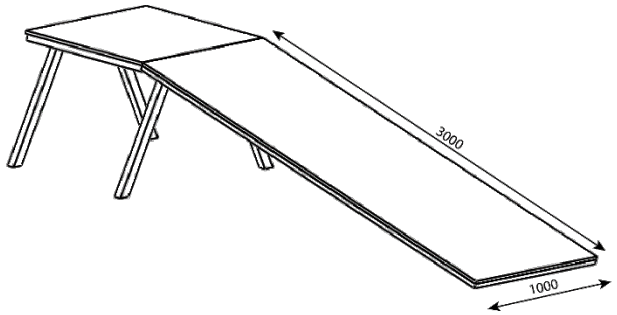

Figure 1 — Basic structure (dimensions are in mm)

The following typologies of uneven terrain are recommended:

a) **Inclined uneven terrain:** Twelve 500 mm x 500 mm modules (see Figure 2) of three different inclinations (5º, 10º or 15º) should be placed in different configurations over the 1000 mm x 3000 mm surface. The following configurations should be used:
   - "A-like" configuration: The modules are placed with lateral inclination, with the highest side at the center of the walkway, creating a ridge in the middle of it (see Figure 3).
   - "V-like" configuration: The modules are placed with lateral inclination, with the highest side at the edges of the walkway, creating a depression in the center (see Figure 4).
   - "M-like" configuration: The modules are placed sequentially with opposing inclinations in the direction of the walkway, creating an alternating up-down pattern (see Figure 5).

b) **Step terrain** (see Figure 6): This condition combines four different heights to simulate steps of 22, 44, 66 and 88 mm. 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.

c) **Soft terrain** (see Figure 7): Two mats with different densities and heights are proposed:
   - Soft-100 configuration: A density of 100 kg/m^3 and a height of 50 mm allows to have a soft, yet reasonably stable surface.
   - 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 base of support.

d) **Unstructured terrain** (see Figure 8): This condition replicates an ecological-like terrain whose surface curvature is continuously changing following an unpredictable pattern.

EXAMPLE 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.

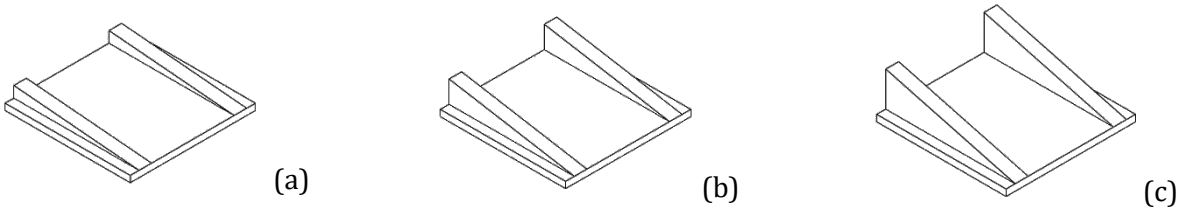

Figure 2 — Inclined modules of 5º (a), 10º (b) and 15º (c) inclination

Material and construction details

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 (or a strip of 22, 44, 66 or 88 mm for the typology step terrain), 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.

The different uneven terrain pattern configurations are shown in Figure 3 to 8.

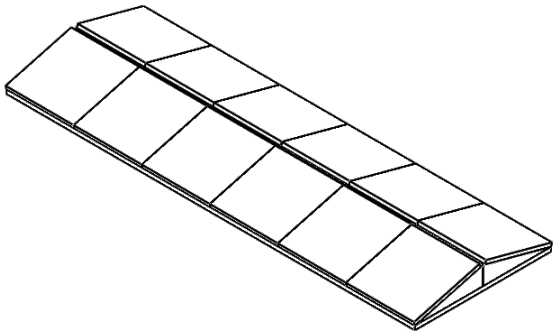

Figure 3 — "A-like" terrain configuration

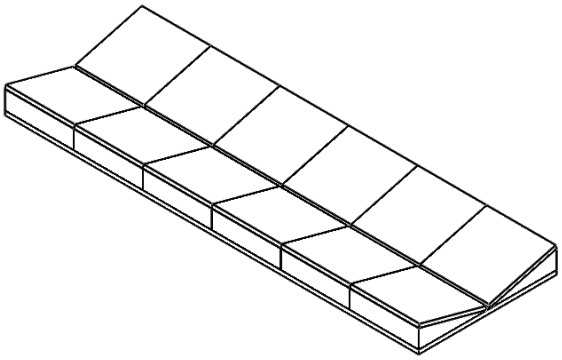

Figure 4 —"V-like" terrain configuration

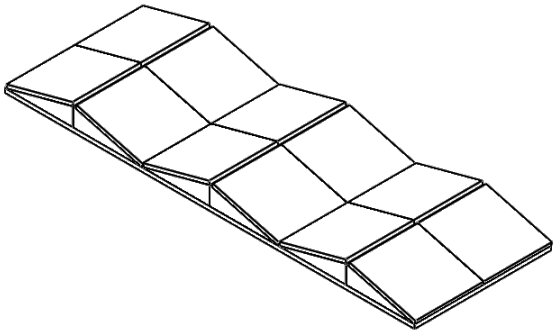

Figure 5 — "M-like" terrain configuration

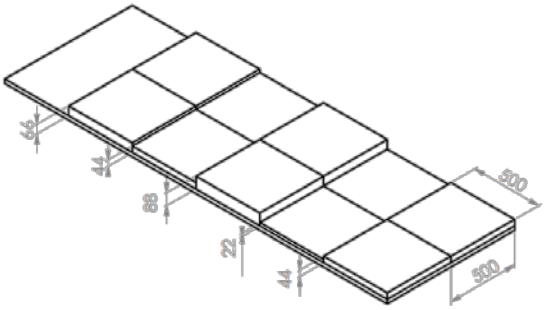

Figure 6 — Step terrain configuration (dimensions are in mm)

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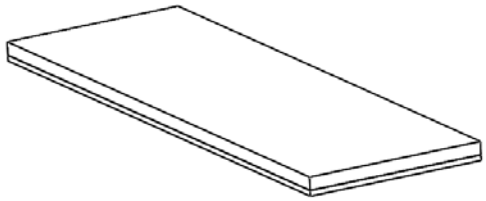

Figure 7 — Soft terrain configuration

Figure 8 — Unstructured terrain configuration

196 # 6 Performance indicators

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

200 **Table 1 — Required performance indicators**

Performance indicator	Description
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 amount of seconds that is needed to complete the trial. Measured in: m/s.
Time to complete	The time that is needed to complete the trial. Measurement unit: s.
Cadence	The number of steps the subject makes per minute. Measured in: steps/min.
Stride duration	The time from initial contact of the leg of interest until the subsequent initial contact of the leg of interest. Measured in: s.
Stance phase duration	Period of time in which the leg of interest has contact with the surface. Measured in: s [or] % of stride duration.
Swing phase duration	Period of time in which the leg of interest has no contact with the surface. Measured in: s [or] % of stride duration.

201

1st double support phase duration	Period of time that starts with the initial contact of the leg of interest 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 leg of interest. Measured in: s [or] % of stride duration.
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 leg of interest. Measured in: s [or] % of stride duration.
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 leg of interest. During this phase the weight is shifted from the leg of interest to the contralateral leg. Measured in: s [or] % of stride duration.

The observations in Table 2 are required to be recorded every time the subject goes through the test bed.

Table 2 — Required observations

Observation	Description
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 can be quantified as the total duration of continuos contact. Measured in: total number [or] seconds.
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: total number.
Number of failed trials	The number of times the subject is not able to complete a trial. Measured in: Binary [0 = fail, 1 = pass].
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: total number.

The following PIs are recommended to be calculated. These indicators may be more difficult to calculate because they require the use of more complex motion capture system and algorithms.

EXAMPLE A stereophotogrammetric system.

210 **Table 3 — Recommended performance indicators**

Performance indicator	Description
Step length	Anteroposterior distance between the heel of the leg of interest at initial contact and the heel of the contralateral leg. Measured in: m.
Stride length	Anteroposterior distance between the heel of the leg of interest at subsequent initial contacts. Measured in: m.
Step width	Medio lateral distance between the lateral side of the foot of interest and the lateral side of the contralateral foot. Measured in: m.
Variation of forward velocity	Interquartile range of the instantaneous forward velocity within a trial. It provides an indication on how much the subject is advancing fluently. Hesitations, stumbles or sudden stops would be reflected in higher values of this PI. Measured in: m/s.
Gait deviation index (GDI)	The GDI, initially conceived to evaluate the gait of children with cerebral palsy [1], has been used as a quantitative parameter of gait pattern changes of individuals with other conditions [2, 3]. The GDI quantifies gait motion with a single parameter based on a kinematic data set [1]. 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.
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) [4]. Measured in: mm/(step/min).
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 [6]. Measured in: adimensional.

211

Margin of stability (MoS)	The MoS 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 P_{CoM} Vertical projection of the center of mass V_{CoM} Velocity of the center of mass g Acceleration of gravity l Leg length The MoS is the distance from XcoM to the boundaries of the BoS [5]. $MoS = \lvert BoS - XCoM \rvert$ where BoS Base of support XCoM Extrapolated center of mass position Measured in: m

7 Procedure

7.1 Testing Conditions

Tests shall be conducted at self-selected normal speed (SNS).

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

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

The tests shall be conducted on at least one uneven terrain configuration, among those specified in Section 5. For each configuration, it is required to perform the test with and without the wearable device. In the context of this document, "without wearable device" means the following:

- If the wearable device is an exoskeleton, then the subject is not wearing any exoskeleton.
- If the wearable device is a prosthesis, then the subject is wearing his/her prosthesis.

Additionally, the execution of the following two baseline conditions is required:

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

7.2 Protocol steps

The protocol consists of multiple trials carried out under identical conditions.

Preparation phase

Before starting the protocol, it is mandatory to have an *enrolment session* where the test technician explains the protocol to the subject and collects the subject's data and protocol conditions (see Section 8).

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

The subject familiarises with the three different conditions below. All three conditions last at least for the "Time of device familiarisation of the subject" defined in the test report (see Section 8).

- Familiarisation with the test bed: The subject familiarises with the test bed walking on the test bed in the different uneven terrain conditions planned in the protocol.
- Familiarisation with the wearable device: The subject familiarises with the device walking over flat floor (Ground Level Walking).
- Familiarisation with the wearable device and the test bed: The subject familiarises with the device walking over the test bed in the different uneven terrain conditions planned in the protocol.

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

Testing phase

After the preparation, enrolment and familiarisation session, the protocol consists of the following steps:

1. The test technician instruments the subject with the selected measurement system. The measurement system should allow the calculation of the required performance indicators (PIs) and any selected optional PIs provided in Section 6.
2. The test technician places the subject at the starting point of the test bed and asks the subject to walk through the test bed at his/her self-selected normal speed (SNS). The test technician collects the testing condition data in the test report, see Section 8. The trial at SNS is carried out first, in order to provide a reference value of the PIs for the subject for the following trials.
3. Repetition of step 2 at SNS and, when considered, at self-selected low speed (SLS) and self-selected high speed (SHS). It is recommended to randomize the sessions by alternating SNS, SLS and SHS conditions to avoid bias and to leave the subject a standard time of rest. The test supervisor shall ensure that the protocol conditions specified in the test report are followed.
4. The subject rests for the standard time of rest that is defined in the protocol condition. The test technician changes the uneven terrain configuration of the test bed according to the list of uneven terrain conditions. The test supervisor shall ensure that the chronological sequence of the terrain setup specified in the test report is followed.
5. The test technician repeats the protocol steps 2 – 4 for all uneven terrain configurations defined in Section 8.
6. The test technician repeats the protocol steps 1 – 5 in the "with the wearable device" condition.
7. The test technician supports the doffing of the wearable device and measurement system from the subject.
8. The test supervisor and the test technician analyse the acquired data and calculate, at least, the required PIs.

8 Test report

The test report is a document intended to collect all the information needed to replicate the protocol (see Section 7). The test report shall be filled out by the test technician for each subject.

Subject data

The following information shall be collected during the *enrolment session*.

- Anthropometric data

- Clinical conditions (e.g. health, neurological disorders, amputee)
- Residual abilities (e.g. mental and physical assessment)
- Ethics documents (e.g. informed consent, GDPR information)

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

Protocol conditions

The following information shall be defined during the *enrolment session*.

- Execution order of the test (testing condition: speed, with/without wearable device)
- List of uneven terrain conditions
- Standard time of subjects' rest
- Time of device familiarisation of the subject
- Number of trials
- Familiarisation time of the subject prior to the testing phase
- Measuring system description
- Wearable device description (e.g. type of device, assistance level, control strategy)

Additional information regarding the protocol can be added.

Testing conditions

The test 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)

Table 4 is an example that should be included in the test report to summarise the trials.

Table 4 — Testing conditions

Trial n°	Speed condition (SNS, SLS, SHS)	Wearable device condition (with or without)	Terrain configuration (GLW, uneven terrain)	Wearable device configuration
#1	SNS	Without	GLW	…
#2	SLS	Without	GLW	…
#3	…	…	…	…

Additional information regarding the testing condition can be added.

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	Name of the PI, e.g. "STEPTIME".
SLOPE	Indication of the support base inclination in degrees. It should be an integer number followed by the ID "UP" or "DOWN" depending on the walking direction, e.g. "12UP".
MODULES	Indication which configuration of the 500 mm x 500 mm modules are adopted. It is composed by the orientation ID (e.g. "A", "V", "M") followed, when applicable, by the inclination of the modules ("5", "10", "15"), e.g. "A15".
SURFACE	Material of the surface touched by the foot, to be chosen among the following IDs: "HARD", "SOFT30", "SOFT100", "UNSTRUCTURED".
DEVICE	Indication whether the subject was wearing the device or not. The possible IDs are "WITH" or "WITHOUT".
SPEED	Indication of the type of selected speed. The possible IDs are "SNS", "SLS", or "SHS".
REPETITION	The ID should include the word "REP" followed by the corresponding cardinal number, e.g. REP1.
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 body side.

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

#18_STEPTIME_12UP_A15_SOFT30_WITH_SNS_REP1_RIGHT=0.89(seconds).

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 – Visualisation of test results

The test technician can use the following visualisation for the graphical result presentation.

Figure 9 shows the results of required PIs in one of the test conditions. The PI values are normalised in order to have a homogenous representation on a scale between 0 to 100 %.

Example PI "Swing Time" normalised with respect to "GLW" condition:

$$normalised\ \text{Swing Time} = \frac{\text{Swing Time}}{\text{Swing Time } in\ GLW}$$

Example PI "Swing Time normalised with respect to "Without wearable device" condition:

$$normalised\ \text{Swing Time} = \frac{\text{Swing Time } with\ device}{\text{Swing Time } without\ device}$$

Example PI "Swing Time" normalised with respect to "SNS" condition:

$$normalised\ \text{Swing Time} = \frac{\text{Swing Time } at\ SHS}{\text{Swing Time } at\ SNS}$$

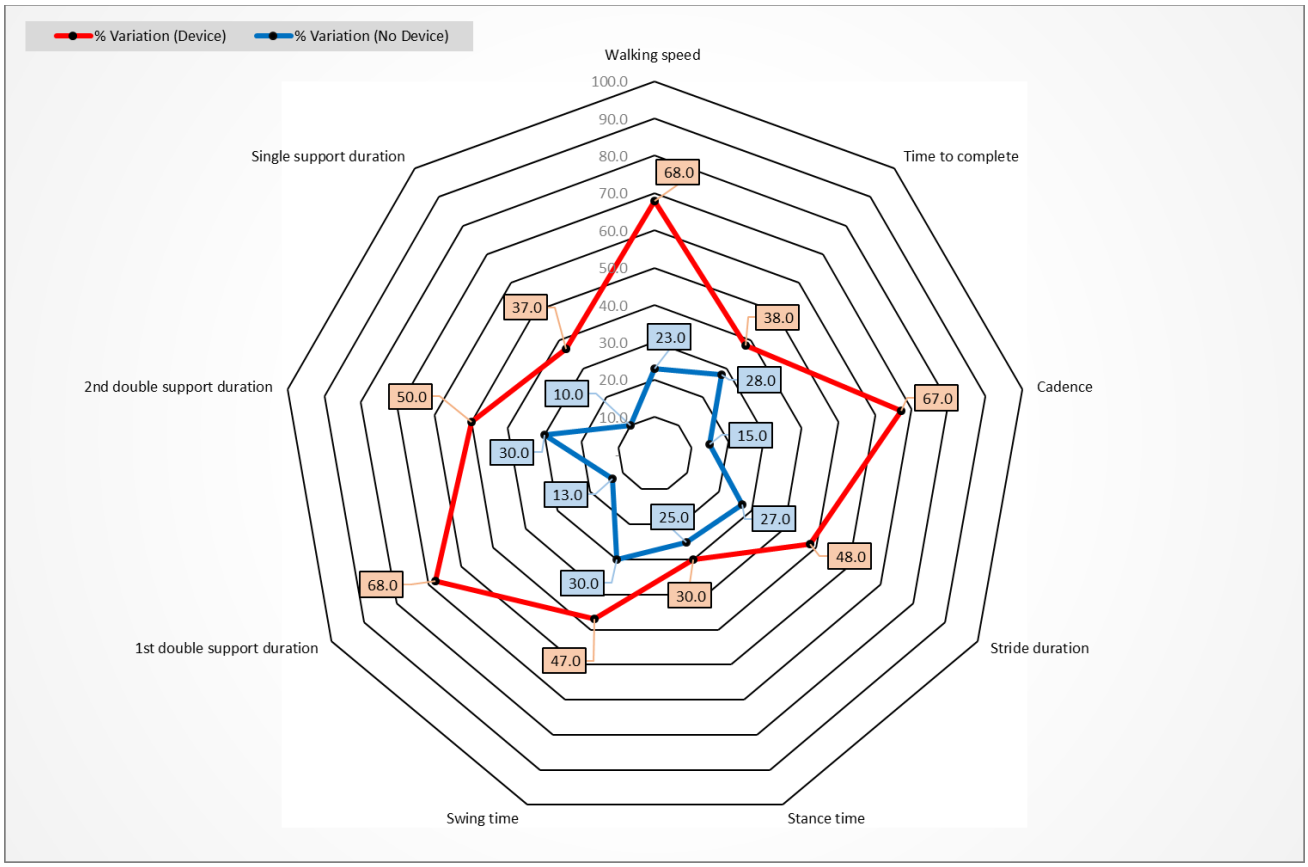

Figure 9 — Visualisation of test results

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