

CEN

CWA 17664

WORKSHOP

April 2021

AGREEMENT

ICS 25.040.30

English version

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

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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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Ref. No.:CWA 17664:2021 E

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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;
- IUVO S.r.l./ Roberto Conti (Vice-Chairperson);
- Automotive Technology Centre of Galicia/ Jawad Masood;
- Axiles Bionics/ Pierre Cherelle, Claire Cherelle;
- Dong-Eui University/ Inhyuk Moon;
- euRobotics aisbl/ Paolo Barattini;
- Hocoma AG (COST Action 16116)/ Jan Veneman;
- Intespring B.V./ Trebsijg Van de Wijdeven;
- Karlstad University/ Jorge Solis;
- Laboratoire national de métrologie et d’essais/ Anne Kalouguine;
- Össur hf/ Freygarður Thorsteinsson, David Langlois;
- Otto Bock SE & Co. KGaA/ Martin Pusch, Simone Oehler;
- Roessingh Research and Development/ Jule Bessler, Erik Prinsen, Gerdienke Prange-Lasonder;
- Sejong University/ Gwak Kwan-Woong;
- SNCF Voyageurs/ Yonnel Giovanelli;
- Technaid S.L./ Javier Roa, Andrés Quesada;
- Tecnalía 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 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/>