FINAL DRAFT International Standard

ISO/FDIS 5363

Robotics — Test methods for exoskeleton-type walking RACA robot

Robotique — Méthodes d'essai du robot ambulant RACA de type exosquelette

ISO/TC **299**

Secretariat: **SIS**

Voting begins on:
2024-01-29

Voting terminates on:
2024-03-25

This draft is submitted to a parallel vote in ISO and in IEC.

Reference number
ISO/FDIS 5363:2024(en)

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Published in Switzerland

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Foreword

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This document was prepared jointly by Technical Committee ISO/TC 299, *Robotics*, and Technical Committee IEC/TC 62, *Medical equipment, software, and systems*, Subcommittee SC 62A, *Common aspects of medical equipment, software, and systems* and Subcommittee SC 62D, *Particular medical equipment, software, and systems*.

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Introduction

When IEC 80601-2-78:2019 was published there were no specific test methods to verify the conformity with the standard. ISO 5363 was developed to supplement IEC 80601-2-78:2019 by specifying test methods to evaluate powered exoskeleton-type walking RACA robots.

Robotics — Test methods for exoskeleton-type walking RACA robot

1 Scope

This document specifies test methods for the exoskeleton-type walking RACA robot used as medical electrical equipment which is intended to move from one location to another, by making reciprocating motion having intermittent contact with the travel surface.

This document does not apply to passive or non-powered exoskeletons.

NOTE These tests can be used to verify conformity with the requirements of IEC 80601-2-78.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

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

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

3.1
actuated applied part
subcategory of applied part that is intended to provide actively controlled physical interactions with the patient that are related to the patient's movement functions, to perform a clinical function of a RACA robot

[SOURCE: IEC 80601-2-78:2019, 201.3.201]

3.2
medical robot
robot intended to be used as medical electrical equipment or medical electrical system

[SOURCE: IEC/TR 60601-4-1:2017, 3.20]

3.3
RACA robot
rehabilitation, assessment, compensation and alleviation robot
medical robot intended by its manufacturer to perform rehabilitation, assessment, compensation or alleviation comprising an actuated applied part

[SOURCE: IEC 80601-2-78:2019, 201.3.212]

3.4
robot
programmed actuated mechanism with a degree of autonomy to perform locomotion, manipulation or positioning

[SOURCE: ISO 8373:2021, 3.1]

3.5
walking
mobile equipment that, once installed and placed into service, is intended to move from one location to another, by making reciprocating motion having intermittent contact with the travel surface and the RACA robot

[SOURCE: IEC 80601-2-78:2019, 201.3.215]

4 Test conditions

4.1 General

The exoskeleton-type walking RACA robot shall be completely assembled, fully charged and operational. It should also be ensured that the robot operates in a safe manner throughout the test.

The tests shall be preceded by the preparations for operation as specified by the manufacturer.

4.2 Environmental conditions

The following environmental conditions shall be maintained during all tests.

— Ambient temperature: 5 °C to 40 °C

— Relative humidity: 15 % to 90 %

If the environmental conditions specified by the manufacturer are outside the given conditions, then this shall be declared in the test results.

4.3 Apparatus

4.3.1 Construction of test equipment

The test apparatus consists of the following parts (see Figure 1):

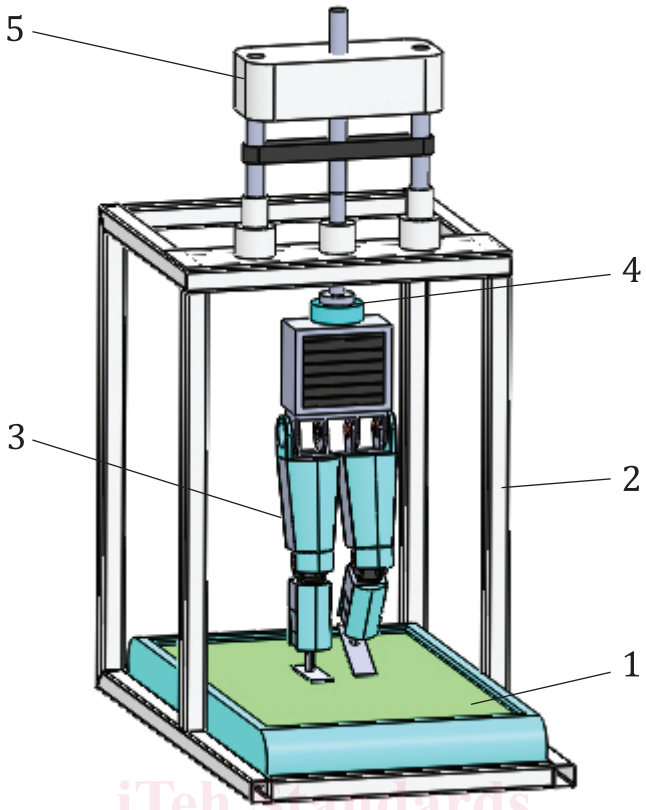
— force sensor to measure floor reaction force;

— actuation module to vertically move the dummy with position control, speed control and force control;

— treadmill to simulate the reciprocating motion;

— test dummy to be attached with RACA robot.

Walking RACA robot shall be installed into the test apparatus.



Key

1 treadmill
2 test frame
3 test dummy
4 force sensor
5 actuation module

Figure 1 — Construction of test equipment

4.3.2 Treadmill

4.3.2.1 Belt speed

The belt speed shall have an accuracy specified by treadmill manufacturer. The belt speed should be able to be controlled in conjunction with the vertical movement of the actuation module.

When the belt speed needs to be controlled by interfacing with the exoskeleton-type walking RACA robot, it should have an input/output terminal of a signal that can be synchronized with the exoskeleton-type walking RACA robot.

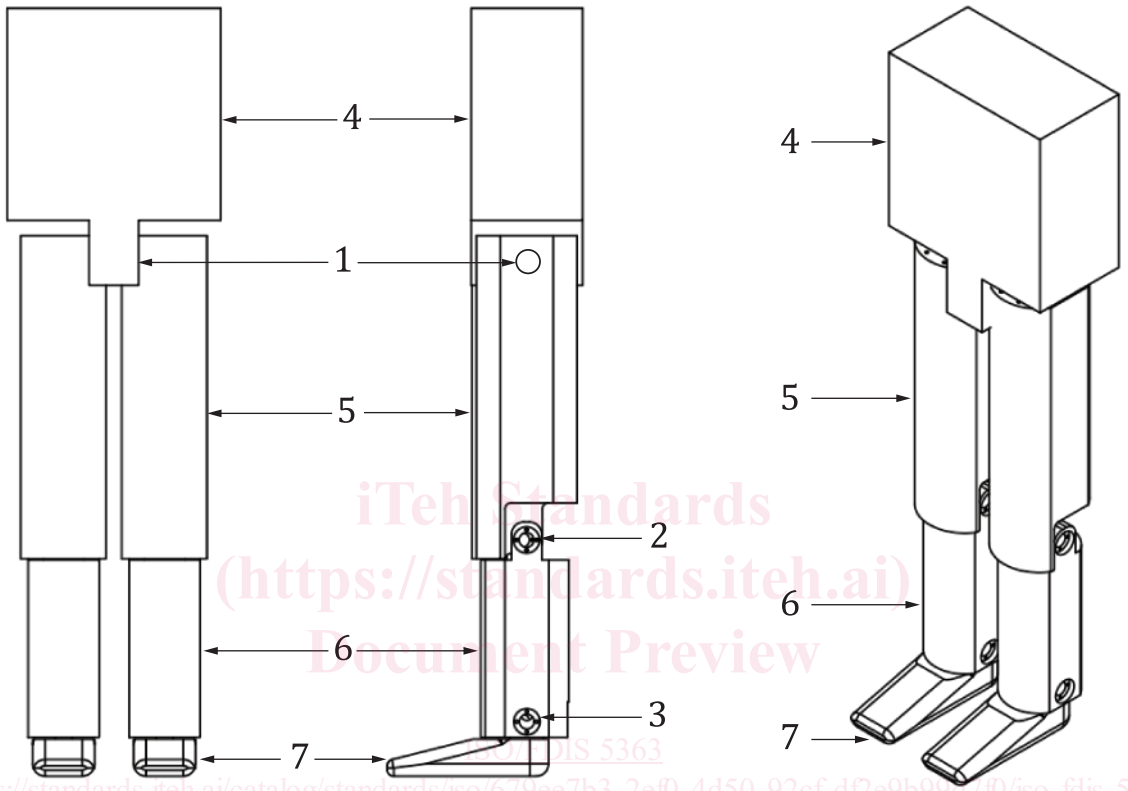
4.3.2.2 Permissible load

The treadmill shall endure the permissible load throughout the test. The permissible load shall be the sum of the maximum allowable patient mass plus mass of robot and mass of accessories as specified by manufacturer's accompanying documents.

4.3.3 Test dummy

The test dummy shall be specified by manufacturer or designed with reference to the distribution of the length and mass of the body segment of IEC 60601-1:2005+AMD1:2012+AMD2:2020, Figure A.19 or the ISO 7250 series.

Figure 2 shows an example of the structure of a test dummy required for the testing of an exoskeleton-type walking RACA robot. The test dummy is a passive type dummy having movable hip, knee, and ankle joints which are coupled by pin or screw joint to allow gait motion. The ankle joints can be either movable or fixed depending on the specification of the robot.



Key

1 hip joint
2 knee joint
3 ankle joint
4 pelvis and upper body
5 thigh
6 shin
7 foot

Figure 2 — Example of structure of test dummy

4.3.4 Test frame

The test frame shall have a rigid structure with sufficient strength to attach or mount the test dummy and the actuation module that lifts the dummy up and down. The test frame shall be fixed on the floor. The test frame shall have sufficient height so that the treadmill can be applied to the bottom of ROBOT while the test dummy is attached. Figure 3 is an example of the structure and dimensions of the test frame.