International Standard

ISO 5363

Robotics — Test methods for exoskeleton-type walking RACA robot

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

First edition
2024-04

Reference number
ISO 5363:2024(en)

Contents

Page

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. This document 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):

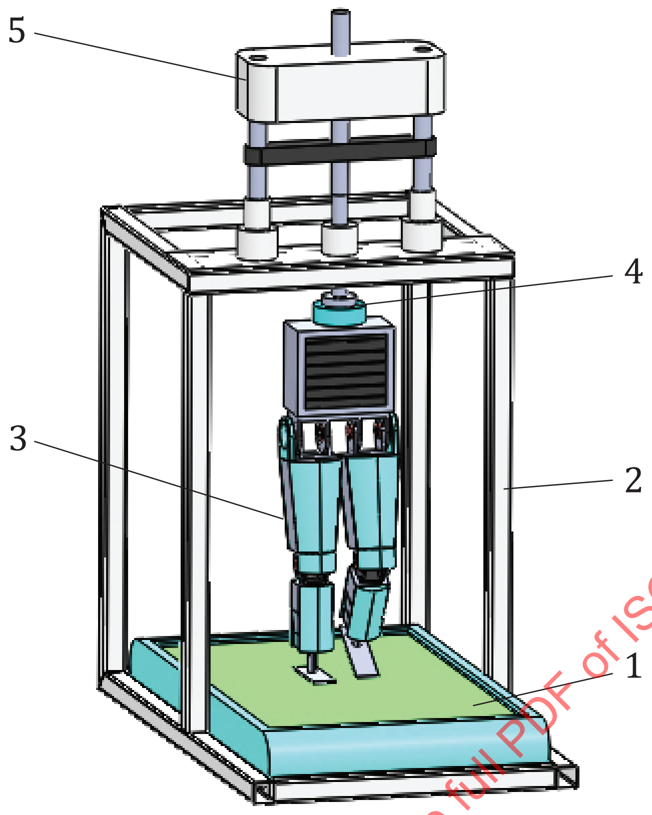
— force sensor to measure floor reaction force;

— 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.

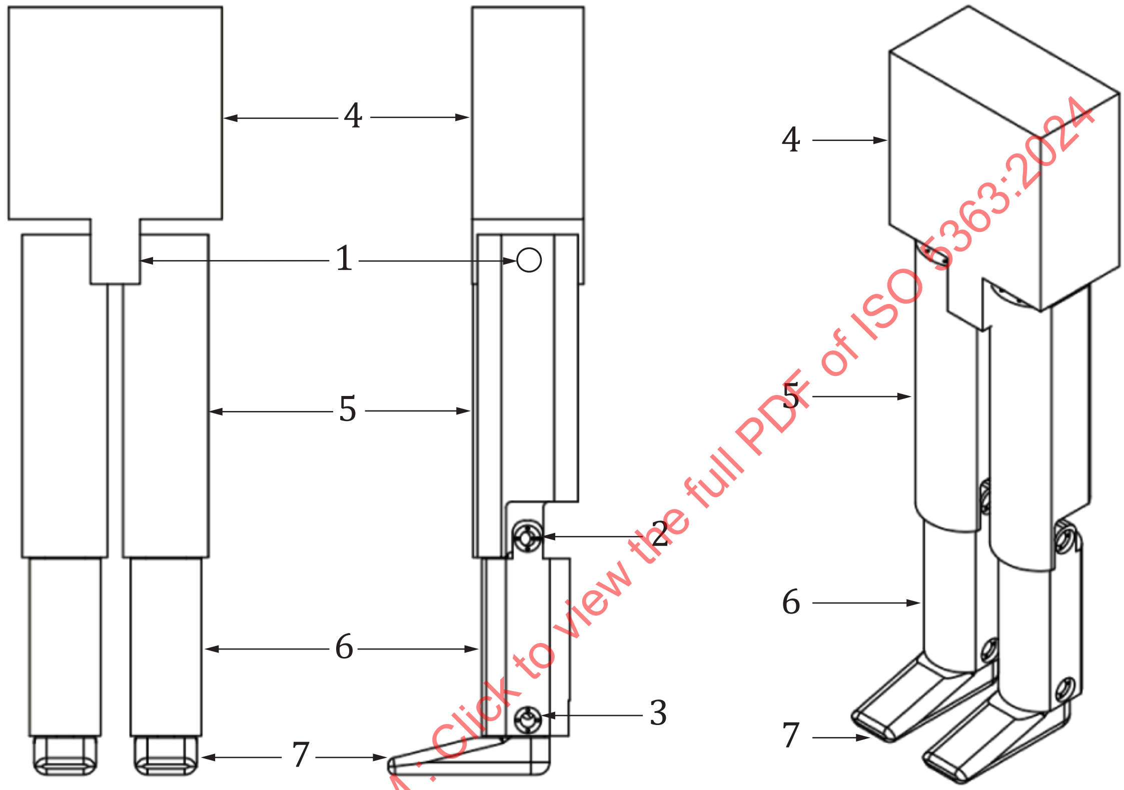
4.3.2.2 Permissible load

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.

Dimensions in millimetres

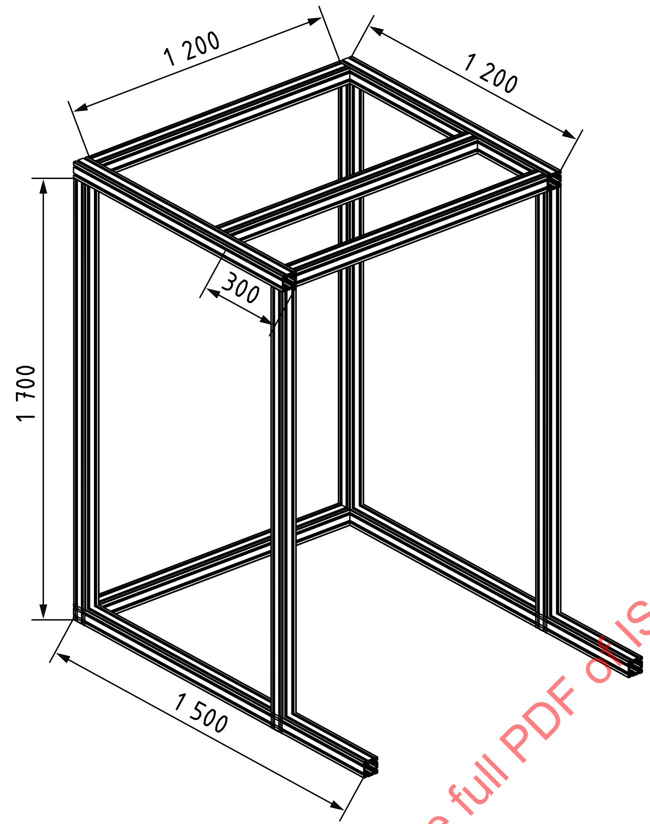


Figure 3 — Example of structure and dimension of test frame

4.3.5 Actuation module

The actuation module is a powered module to lift the test dummy up and down to assist gait motion, and the speed should be controlled in conjunction with the walking speed of the walking RACA robot. The vertical moving range of the actuation module should be 100 mm or more to provide clearance under foot. When the exoskeleton-type walking RACA robot is tested in conjunction with the speed of the treadmill, there shall be a mechanism to interlock the motion speed of the actuation module, the walking speed of walking RACA robot and treadmill speed.

4.4 Example of test setup

The walking RACA robot to be tested shall be worn on the test dummy as specified by the manufacturer. The bottom of the feet of RACA robot shall be in contact with the treadmill.

Figure 4 shows an example of a walking RACA robot mounted on a test dummy.

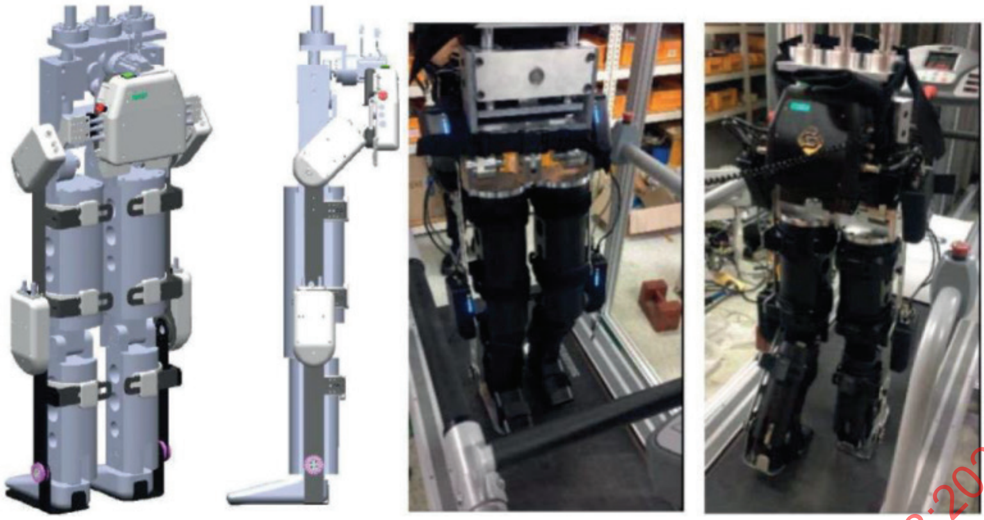


Figure 4 — Example of test setup

5 Accuracy test of range of movement of each joint of walking RACA robot

5.1 Purpose

This test is intended to measure the accuracy of range of movement of each joint of the walking RACA robot. This test can apply to walking RACA robots applying positional control for its joint.

5.2 Procedure

The movement of joint angles of the walking RACA robot is measured by a measuring instrument (e.g., a 3D optical motion analyser).

If an electric-goniometer is utilized for measuring a hip joint angle, the electric-goniometer is set to the trunk and thigh parallel, but the center of the electric-goniometer may be set to the rotation axis of the hip joint.

The range of movement of each joint shall be specified by manufacturer before testing.

The range of movement of each joint shall be measured during gait motion under the worst condition specified by manufacturer.

NOTE The worst condition can include the maximum load, the maximum speed, and the maximum gait length, etc.

The accuracy of range of movement of each joint of the walking RACA robot shall meet the performance specifications specified by the manufacturer.

EXAMPLE The performance specifications can be 25° ± 5° for the range of motion of the hip joint, 40° ± 5° for the range of motion of the knee joint, and 20° ± 5° for the range of motion of the ankle joint.

6 Repeated durability test of actuated applied part

6.1 Purpose

The actuated applied part that performs repetitive movements shall be verified by fatigue or durability tests as a means of control of unacceptable risks due to premature failure in the expected service life (see IEC 80601-2-78:2019, 201.9.8.1).

This test is intended to verify the durability of actuated applied part during the period between two successive inspections.

NOTE This test is considered as validation of the mechanical design of the actuated applied part. The mechanical design of walking RACA robots is based on the total load, which is identified by manufacturers in accordance with IEC 80601-2-78:2019, Annex AA, 201.9.8.

6.2 Procedure

The test dummy is loaded to the actuated applied part. And the test walking speed is set to a pre-set speed suggested by manufacturer. For this test, an external power supply may be used instead of the internal power source in order not to stop the test due to a power loss or battery depletion. In this case, it shall be recorded in the test report.

The exoskeleton-type walking RACA robot is attached to test dummy, and the treadmill speed shall be synchronized to the walking motion of the walking RACA robot.

The number of repetitions is executed until it reaches the number specified by the manufacturer.

If the test is difficult to proceed due to a failure, damage, or breakdown of the RACA robot while testing, the test stops immediately. All events in the test shall be recorded.

NOTE The number of repetitions can be based on the number of contacts on the floor between maintenance cycles (ISO 13823 can be referred to).

7 Repeated durability test of support system of walking RACA robot

7.1 Purpose

This test is intended to test the durability of the support system of a walking RACA robot against impact forces on its foot parts, by simulating the landing impact on the floor during walking movements.

NOTE The support systems here mentioned include actuation systems and actuated applied parts shown in of IEC 80601-2-78:2019, Figure AA.18.

7.2 Procedure

The walking RACA robot is affixed onto a dummy either standing upright or placed horizontally, and impact force is applied to the foot parts of the walking RACA robot repeatedly, for a designated number of impacts.

NOTE 1 If the dummy is placed vertically to the floor and use free fall to create impact force, the height from the floor can be used as a parameter to adjust the impact force.

NOTE 2 If the dummy is placed horizontally to the floor in order to reduce gravity effect, a force servo mechanism can be used to adjust the impact force. An example of such a case is shown in Annex B.

The impact force to be applied to the foot part (per foot) is calculated as the sum of the maximum allowable patient mass and the mass of the RACA robot, multiplied by 1,6 (refer to A.2 for the theoretical background).

$$F = M \times 1{,}6 \times g$$

$$M = M_{\mathrm{M}} + M_{\mathrm{R}}$$

where

F	is the impact force [N];
M_M	is the maximum allowable patient mass [kg];
M_R	is the mass of RACA robot [kg];
g	is the gravity acceleration [m/s^2].

The maximum allowable patient mass specified by manufacturer shall apply in accordance with accompanying documents. Unless otherwise stated by the manufacturer, a mass of 135 kg for adult patients shall be used.

NOTE 3 Refer to A.3 for an example on how to estimate the number of impacts throughout the expected service life.

8 Test report

The test conditions, speed, angle of each joint in the actuated applied part and the number of repetition tests should be recorded.

The test report shall include the items listed in Table 1. Additional information can be added to the test report as necessary.

Table 1 — Minimum test report contents

No.	Item	Additional detail
1	Title and Report number	
2	Date of issue of Report	
3	Total number of pages	
4	Name and location of the test laboratory/ facility	
5	Name of manufacturer and address (test item)	
6	Test item description	Include the trade marks, model / type and part number as applicable
7	Ratings - Nameplate/marking plate information	Exoskeleton: Vdc, A, A-hr, duty cycle, maximum speed, maximum safe working load (permissible load) Charging station: V, Hz, A or VA
8	Classification of installation of use	Exoskeleton: Walking Charging station: transportable / portable / stationary / mobile / fixed / permanently installed.
9	Supply connection	Exoskeleton: Internally powered (batteries or battery pack) Charging station: permanently installed / appliance coupler / non-detachable cord
10	Intended use	Including type of patient, clinical application and patient location
11	Environmental conditions	Outside/Inside/Home Healthcare/ IP rating
12	Mode of operation	Continuous / non-continuous/ duty cycle / maximum operating / usage time (autonomy)
13	Software/firmware version	
14	Accessories and detachable parts included	
15	Other options include	
16	General product information and other remarks	

Table 1 *(continued)*

No.	Item	Additional detail
17	Test equipment used, including test equipment accuracy (technical specifications) and calibration certificates	ISO/IEC 17025:2017 including as applicable the measurement uncertainty (MU) 1) Tread mill 2) Test Frame 3) Test dummy (including weights) 4) Force sensors 5) Actuation module 6) All other test equipment used during testing
18	Date of receipt of test item and testing dates	
19	Test item setup/configuration during the test, including if appropriate a block diagram	Test setup (photographs)
20	Documentation of any special test item hardware or software needed to perform the tests including deviations/exclusions	Adapted testing
21	Test conditions/settings and operating modes during testing	Testing criteria (based on technical specifications claimed by manufacturer) Document for each test: speed, angle of each joint in the actuated applied part, the number of repetition and other relevant testing parameters
22	Test results for measurements of Walking RACA robot movements as per Clause 5	Testing result table (with the appropriate units of measurement)
23	Test Results for repeated durability test of actuated applied part as per Clause 6	Testing result table (with the appropriate units of measurement)
24	Test Results for repeated durability test of support systems as per Clause 7	Testing result table (with the appropriate units of measurement)
24	Effects on the test item that were observed during or after the application of the test, and where appropriate, opinions and interpretations.	For each test: testing observation notes
25	Where relevant, a statement of conformity with requirements or specifications	To which testing results the statement of conformity applies (pass/ fail verdict)
26	Names and functions or equivalent identification of the persons performing the testing, reviewing and persons approving the test report including dates	For each test: tested by, reviewed by For overall approval: approved by, authorized by
NOTE	This table provides additional details to ISO/IEC 17025:2017, 7.8.	

Annex A
(informative)

Theoretical background of the repeated durability test of support systems of walking RACA robot

A.1 General

There can be other methods to demonstrate sufficient durability of a walking RACA robot. The necessary durability depends on the intended use and indications of each particular walking RACA robot.

There are two important aspects when verifying the sufficiency of durability:

a) Worst case: The verification should take into account the worst case specified by the manufacturer's design specifications (e.g. maximum allowable patient mass, maximum speed, and maximum force).

b) System approach: The verification should take into account that the true safety of the device shall be evaluated as a whole and cannot be presented by verification results of each component only (components can behave differently once used in unison).

This annex provides an example of durability verification, bench test that simulates repetitive landing impact on the entire device. For certain devices, this verification method covers both aspects and can be a useful method to demonstrate that the device is equipped with sufficient durability to endure the impact and stress expected to be applied during its lifetime under intended use.

This is not appropriate to verify durability for walking RACA robots that are intended for running or jumping.

A.2 Rationale of the factor 1,6 for the impact force

In 7.2, the impact force on the foot part during the test is calculated as the sum of the maximum allowable patient mass and the mass of the RACA robot, multiplied by 1,6. This factor 1,6 is based on the data of References [6] and [7]. By evaluating these test results[6,7], the maximum factor of the impact forces on the foot during walking is the body mass multiplied by 1,6 maximum.

A.3 Example of how to estimate number of impacts

In this test, the number of steps that can be tolerated by the device over its expected service life, and the load on the frame needs to be determined.

The number of steps that occur is estimated by the following calculation:

a) Walking speed

Generally, the range of walking speed for rehabilitation of ambulatory dysfunction is about 0 m/s to 0,56 m/s, and assuming a normal distribution, the average walking speed is 0,28 m/s.

b) Rate of active walking

Furthermore, the wearer is not always walking while they wear the RACA robot. A coefficient to adjust the time for the wearer taking rests can also be used.

c) Walking distance

Taking these into consideration, the maximum walking distance over the expected service life can be calculated as follows:

$$D = V \times T \times R$$

where

D	is maximum walking distance over the expected service life [m];
V	is the average walking speed [m/s];
T	is the maximum time of use [s];
R	is the rate of active walking.

d) Number of maximum steps

The maximum number of steps for a single leg can be calculated as follows:

$$S = \frac{D}{2L}$$

where

S	is the maximum number of steps for a single leg;
D	is maximum walking distance over the expected service life [m];
L	is the stride length.