

INTERNATIONAL
RECOMMENDATION

OIML R 128

Edition 2000 (E)

Ergometers for foot crank work

Ergomètres à pédalier



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Foreword

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Ergometers for foot crank work

1 Scope

This OIML Recommendation applies to ergometers for foot crank work (foot crank ergometers) used in the medical field for the defined and reproducible physical stressing of subjects (patients). It is intended to define minimum requirements for the performance and efficiency of these devices and to achieve accurate and comparable medical results.

2 References

This Recommendation incorporates undated references from other publications. These references are cited at the appropriate places in the text and the publications are listed below. The latest edition of the publication referred to applies.

- IEC 60601-1-2 Medical electrical equipment - Part 1: General requirements for safety - 2. Collateral Standard: Electromagnetic compatibility - Requirements and tests.
- IEC 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements.
- International Vocabulary of Basic and General Terms in Metrology (VIM).

3 Definitions

VIM terms apply.

3.1 Ergometers for foot crank work (foot crank ergometers)

Foot crank ergometers are devices that are equipped with a pedal arrangement, a braking device and an indicating device. They are used for the defined and reproducible physical stressing of subjects (patients).

3.2 Foot crank ergometers with controlled braking power

Foot crank ergometers with controlled braking power are ergometers whose input power at the crankshaft is independent of the rotational frequency within a specified working range.

3.3 Foot crank ergometers with controlled braking torque

Foot crank ergometers with controlled braking torque are ergometers whose braking torque is independent of the rotational frequency. Their input power at the crankshaft is proportional to the rotational frequency.

3.4 Basic saddle position S

The basic saddle position S is defined by the vertical distance \overline{CS} from the center C of the foot crank bearing to the surface of the saddle and by the angle α (see Fig. 1).

3.5 Basic handle position H

The basic handle position H is defined by the vertical distance \overline{CH} from the center C of the foot crank bearing to the handle connection point and by the horizontal distance \overline{SH} from the saddle position S to the handle connection point (see Fig. 1).

3.6 Foot crank length L

The foot crank length L is the length between the center C of the crank bearing and the center of the pedal shaft (see Fig. 1).

3.7 Angle α

The angle α is the angle between the saddle-height adjustment direction (seat tube) and the vertical (see Fig. 1).

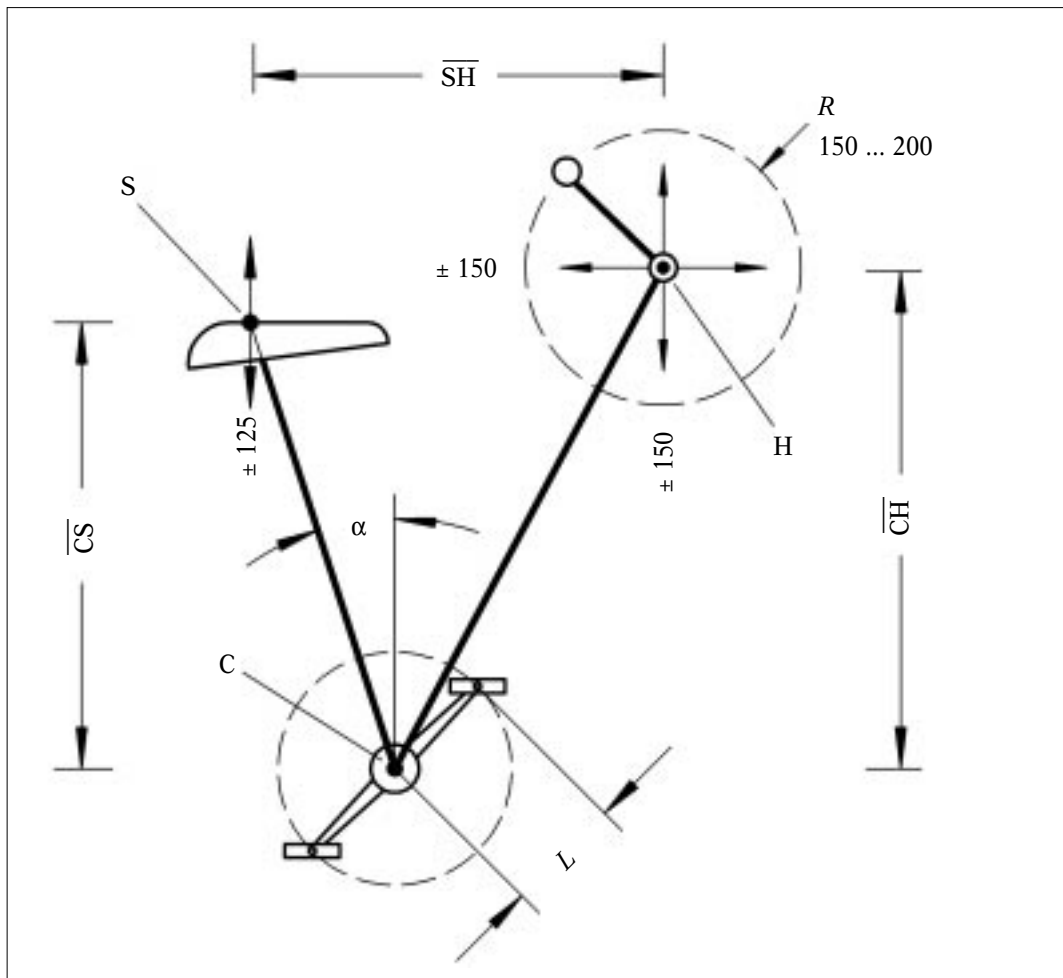


Fig. 1 Definition of basic saddle position S, basic handle position H and centre of foot crank bearing C (dimensions in mm).

3.8 Absorbed braking power

The absorbed braking power is the mechanical input power of the ergometer at the crankshaft and is measured and displayed by the test equipment.

4 Measurands and units

The physical power P which is delivered by a subject to the foot crank ergometer is obtained from the product of the braking torque M at the foot crank and the rotational frequency n of this foot crank according to the equation

$$P = M \cdot 2 \cdot \pi \cdot n / 60.$$

The physical power shall be indicated in watt (W), the braking torque in newton metre (N·m) and the rotational frequency in revolutions per minute (min^{-1}).

5 Requirements

5.1 Mechanical requirements

5.1.1 The adjustment of the saddle and handles shall be possible without using tools. Precautions shall be taken to prevent the saddle and the handles from accidentally loosening.

5.1.2 The saddle (surface of the saddle) shall be adjustable in a minimum vertical range of +125 mm to -125 mm relative to the basic saddle position S (see Fig. 1).

The vertical distance \overline{CS} between the center line of the foot crank bearing and the basic saddle position S may vary vertically from 600 mm to 700 mm due to the different physical builds of subjects.

5.1.3 The angle α shall be in the range from 13° to 26° .

5.1.4 The handles shall be adjustable either:

a) in a minimum vertical range of ± 150 mm (and should be adjustable in a minimum horizontal range of ± 150 mm) relative to the basic handle position H,

or

b) at least in a circular line with the radius R in the range from 150 mm to 200 mm with its center at the basic handle position H.

The vertical distance \overline{CH} between the center line of the foot crank bearing and the basic handle position H may vary vertically from 675 mm to 775 mm due to the different physical builds of the subjects (patients).

5.1.5 The horizontal distance \overline{SH} between the basic saddle position S and the basic handle position H shall be in the range from 450 mm to 750 mm.

5.1.6 The foot crank length L shall be between 160 mm and 175 mm. The distance between the right and left foot cranks shall be less than 200 mm.

5.1.7 Foot crank ergometers shall have a freewheel transmission.

Note: Testing of compliance with the mechanical requirements in 5.1.1 to 5.1.7 shall be carried out by measuring the distances and the angle, and by visual inspection.

5.1.8 For ergometers with adjustable power P , the effective moment of inertia of the flywheel on the crankshaft shall be:

- in the range from $5.5 \text{ kg}\cdot\text{m}^2$ to $13 \text{ kg}\cdot\text{m}^2$ for $P \leq 400 \text{ W}$; and
- in the range from $5.5 \text{ kg}\cdot\text{m}^2$ to $20 \text{ kg}\cdot\text{m}^2$ for $P > 400 \text{ W}$.

Testing shall be carried out in accordance with 7.3.4.

5.2 Metrological requirements for the indicating device

The display shall be designed and arranged such that the information, including measured values, can be easily read and recognized.

5.2.1 The following values shall be continuously indicated on the indicating device:

a) in the case of ergometers with controlled braking power (see 3.2): the power setpoint and the measured rotational frequency;

b) in the case of ergometers with controlled braking torque (see 3.3): the braking torque setpoint and the measured rotational frequency, or the measured power and the measured rotational frequency.

It shall be possible to determine the corresponding power at least for the rotational frequencies of 50 min^{-1} , 60 min^{-1} and 70 min^{-1} , e.g. by using a table or a graph.

5.2.2 A rotational frequency indicator shall be permanently visible to the subject (patient). The display shall be designed and arranged such that this value can be read and easily recognized.

5.2.3 The indication of measured values shall be damped. The transition time for 50 % of the transient shall be between 0.5 s and 1.5 s. Digital indicators shall change at a rate from 0.5 Hz to 2 Hz.

5.2.4 After a new braking power or braking torque setpoint has been chosen, it shall be indicated immediately.

5.2.5 For the indication of power, the scale interval or the digital resolution shall be $\leq 5 \text{ W}$. For ergometers with controlled braking torque and analog indication of power, the scale interval shall be $\leq 10 \text{ W}$.

5.2.6 For the indication of the rotational frequency greater than or equal to 40 min^{-1} , the scale interval or digital resolution shall be $\leq 2 \text{ min}^{-1}$.

Notes: Testing of compliance with the requirements for the indicating device (5.2.1, 5.2.2 and 5.2.4 to 5.2.6) shall be carried out by visual inspection.

Testing of compliance with the requirements for the indicating device (5.2.3) shall be carried out by measuring the transient time with a stopwatch.

5.3 Metrological requirements for ergometers

5.3.1 A semi-automatic or automatic self-checking facility, verifying the correct operation of the electronic system, shall be available for the user or the correct operation shall be tested automatically after the device has been switched on.

Testing shall be carried out by visual inspection.

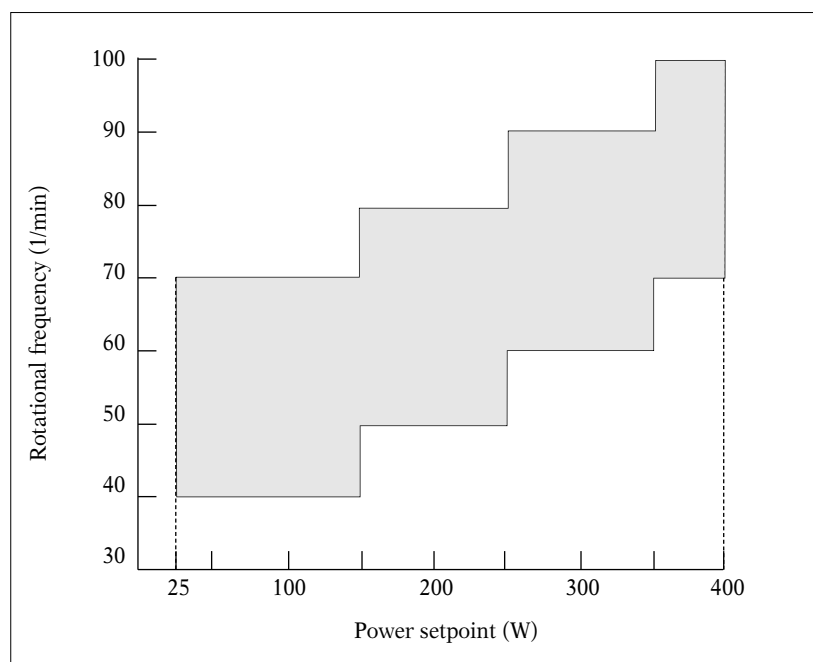


Fig. 2 Working range of the braking power control (see 5.3.2)

5.3.2 The minimum working range of the braking power shall be from 25 W to 250 W. The maximum permissible error of the absorbed braking power defined in clause 6 applies for the whole range of the braking power specified by the manufacturer in the documentation.

For ergometers with controlled braking power (see 3.2) the braking power control shall work independently of the rotational frequency in the area defined by two limiting graphs (see Fig. 2).

Testing shall be carried out in accordance with 7.3.1.

5.3.3 Manual setting of the power setpoint shall be possible in steps not greater than 5 W.

Testing shall be carried out by visual inspection and in accordance with 7.3.1.

5.3.4 If the rotational frequency is changed in its working range, the absorbed power shall stabilize within 5 s to the power setpoint within the error limits defined in clause 6.

Testing shall be carried out in accordance with 7.3.6 a).

5.3.5 After switching to another power setpoint, the absorbed power shall stabilize within 10 s to the new power setpoint within the error limits defined in clause 6.

The gradient of the power change shall be smaller than 50 W/s.

Testing shall be carried out in accordance with 7.3.6 b).

5.3.6 After finishing the stressing of the subject, the absorbed braking power shall drop down within a time greater than 3 s, but the gradient of the power change shall be less than 100 W/s.

Testing shall be carried out in accordance with 7.3.6 c).

5.3.7 The braking power control shall operate within the error limits defined in clause 6 in the working range during and after continuous stressing.

Testing shall be carried out in accordance with 7.3.2.

5.3.8 The braking power control for adjustable braking powers greater than 400 W shall work within the error limits defined in clause 6 in the working range during and after performing the interval test.

Testing shall be carried out in accordance with 7.3.3.

5.3.9 The indication of rotational frequency shall be within the error limits defined in clause 6.2.

Testing shall be carried out in accordance with 7.3.5.

5.4 Technical requirements

5.4.1 Sealing

All controls that may have an effect on the metrological function of the instrument shall be sealed to protect against unauthorized access.

Testing shall be carried out by visual inspection.

5.5 Immunity against influence quantities

5.5.1 Signal input and signal output parts (excluding internal interfaces)

The design of foot crank ergometers shall ensure that any incorrectly connected or defective optional equipment or a short-circuit of signal outputs and signal inputs does not cause errors larger than those given in clause 6 for:

- the power indication;
- the power input at the crankshaft; and
- the rotational frequency indication,

unless the indications can be clearly recognized as being definitely incorrect.

Testing shall be carried out in accordance with 7.3.7.

5.5.2 Electromagnetic compatibility

The design of foot crank ergometers shall ensure that in the presence of:

- electric and electrostatic interferences (e.g. bursts, spikes, electrostatic discharges);
- electromagnetic interferences; and
- magnetic interferences,

the requirements in clause 6 for:

- the power indication;
- the power input at the crankshaft; and
- the rotational frequency indication

shall be fulfilled,

unless the indications can be clearly recognized as being definitely incorrect.

Testing shall be carried out in accordance with IEC 60601-1-2.

6 Maximum permissible errors

6.1 Absorbed braking power

The maximum permissible error of the absorbed braking power shall be 5 % or 3 W, whichever is greater.

- a) In case of controlled braking power (see 3.2) the error refers to the power setpoint of the ergometer.
- b) In case of controlled braking torque (see 3.3) the error refers to the indicated power of the ergometer or the product of the indicated torque and the rotational frequency (see the equation in 4).

The error of the test equipment (7.2) shall not be taken into account when testing the maximum permissible error.

6.2 Indication for rotational frequencies

The maximum permissible error of indication for rotational frequencies greater than 20 min⁻¹ shall be 2 min⁻¹.

7 Pattern approval

7.1 Documentation

The documentation submitted with the application for pattern approval shall include:

- instructions for operation, with the essential technical parameters;
- figures and/or drawings and a description of the mechanical design, especially of the metrologically relevant parts;
- documentation of electronic design, especially of the signal flow and the principle of power regulation; and
- information about how to set the setpoints in accordance with the test procedures in 7.3.

7.2 Test equipment

It shall be possible for the test equipment to determine the power absorbed by the ergometer at the crankshaft while a drive transmits power to the crankshaft at controlled constant rotational frequency.

The maximum error of the test equipment for determining the power absorbed by the ergometer resulting from the braking torque and the rotational frequency shall not exceed 2 % or 2 W, whichever is greater.

The maximum error of the test equipment for determining the rotational frequency shall not exceed 0.5 min⁻¹.

7.3 Test procedures

7.3.1 Test for compliance with the requirements on the maximum permissible errors to be met by the ergometer

Measurements of the absorbed braking power shall be carried out at least at the following setpoints and in chronological order:

- a) after switching on the ergometer which is at ambient temperature

25 W, 50 W, 75 W, 100 W, 150 W, 200 W and 250 W at 70 min⁻¹

- b) after 10 min warm-up time at 250 W at 80 min⁻¹

25 W, 50 W, 75 W, 100 W, 150 W at 40 min⁻¹

25 W, 50 W, 75 W, 100 W, 150 W, 200 W and 250 W at 50 min⁻¹

25 W, 50 W, 75 W, 100 W, 150 W, 200 W and 250 W at 60 min⁻¹

25 W, 50 W, 75 W, 100 W, 150 W, 200 W and 250 W at 70 min⁻¹

150 W, 200 W and 250 W at 80 min⁻¹

250 W at 90 min⁻¹

At setpoints greater than 250 W, the increase of the setpoints shall be in steps of 50 W.

Each measurement at the setpoint power shall be represented by the mean value of at least 3 single measurements of the absorbed braking power. Each single measurement shall be averaged over at least 3 complete revolutions of the foot crank.

7.3.2 Continuous stress test

The foot crank ergometer shall be subjected to a continuous stressing at the four setpoints:

- a) 50 W at 50 min⁻¹;
- b) 100 W at 50 min⁻¹;
- c) 150 W at 60 min⁻¹; and
- d) 250 W at 70 min⁻¹.

At each setpoint the continuous stressing shall last 2 hours followed by a cooling-off time of 30 min at the rotational frequency 0 min⁻¹.

The absorbed braking power shall be recorded during the whole test.

The continuous stress test shall be carried out at an ambient temperature between 20 °C and 25 °C.

7.3.3 Interval test

Foot crank ergometers for adjustable power setpoints greater than 400 W shall be subjected to an interval test (10 min stressing at 80 % of the maximum adjustable power, alternating with 5 min cooling-off at the rotational frequency 0 min⁻¹) of 2 hours.

The absorbed braking power shall be recorded during the whole test.

The interval test shall be carried out at an ambient temperature between 20 °C and 25 °C.

7.3.4 Effective moment of inertia

The manufacturer shall describe the method of determination of the effective moment of inertia.

Note: The effective moment of inertia Θ of the flywheel on the crankshaft can be calculated from the measured absorbed energy E to accelerate the flywheel to a defined rotational frequency n according to the equation:

$$\Theta = 2 \cdot E / (2 \cdot \pi \cdot n / 60)^2$$

when all braking forces are switched off or disconnected.

7.3.5 Test of rotational frequency indication

The indication of rotational frequency shall be tested in steps of 10 min⁻¹ from 30 min⁻¹ to 100 min⁻¹ at the braking power of 100 W.

7.3.6 Test of transient times

The tests for compliance with the transient time requirements to be met by the ergometer are:

- a) subclause 5.3.4 shall be tested by recording the transient time and the gradient of the absorbed braking power when changing the rotational frequency repeated from 50 min⁻¹ to 60 min⁻¹ and vice versa;
- b) subclause 5.3.5 shall be tested by recording the setting time to reach the new setpoint and the transient time of the absorbed braking power when changing the setpoint repeated from 25 W to 250 W and vice versa; and
- c) subclause 5.3.6 shall be tested by recording the transient time and the gradient of the absorbed braking power when changing the setpoint repeated from the maximum adjustable power to the setpoint 0 W or to the minimum braking power.

7.3.7 Test of external influences

The tests for compliance with the requirements to be met by the ergometer in accordance with 5.5.1 shall be carried out by recording the absorbed braking power when:

- a) short-circuiting all signal input pins and signal output pins of the interface connector, one with each other; and
- b) applying 30 V DC or the maximum permissible voltage specified by the manufacturer to each signal input pin and signal output pin of the interface connector (see 9.2).

The test shall be carried out in accordance with 7.3.1 at least at the setpoint $P = 100 \text{ W}$ and $n = 60 \text{ min}^{-1}$.

7.4 Model of Test Report: See Annex A.

7.5 Number of ergometers to be submitted for the test: 1 device.

8 Initial and subsequent verification

8.1 Test equipment: Subclause 7.2 shall apply.

8.2 The test of the conformity of the ergometer with the approved pattern shall be carried out by visual inspection based on the type approval certificate.

8.3 Test of the essential ergometer function

Power on, setpoint: 100 W; begin with crank work at 50 min^{-1} and change to crank work at 80 min^{-1} , effect: controlled braking torque shall change.

8.4 The test of the maximum permissible error (clause 6) of the indication of the rotational frequency shall be carried out at 60 min^{-1} .

8.5 Test for compliance with the maximum permissible error (clause 6) to be met by the ergometer according to subclause 7.3.1, but reduced to:

- a) measurements at the setpoints 25 W and 150 W both at all possible rotational frequencies (in steps of 10 min^{-1}) of the working range;
- b) after 5 min warm-up at the setpoint 200 W at 60 min^{-1} , measurements at the power 25 W, 50 W, 100 W, 150 W and 250 W always at the rotational frequency of 60 min^{-1} .

8.6 Test of transient times shall be carried out in accordance with subclause 7.3.6 c).

8.7 It is recommended that the subsequent verification is carried out every two years, after repair or after breaking any seals.

9 Information supplied by the manufacturer

9.1 General

If symbols are used, they shall be in accordance with IEC 61010-1.

9.2 Documentation provided by the manufacturer for the user

The documentation provided by the manufacturer shall contain the following information:

- a) reference to this OIML Recommendation including the complete title;
- b) detailed instructions required for correct operation;
- c) nature and frequency of verifications and maintenance to ensure that the instrument operates correctly and safely at all times;
- d) technical data; and
- e) electrical specifications of the input and output signals.

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PTB-Mitteilungen 105, 6/95
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H.J. Thiemich, J. Tilgner
OIML Bulletin, Volume XXXVII, No. 1, Jan. 1996
- *Entwicklung einer Kalibriereinrichtung
für Ergometerprüfstände*
H. Pfeiffer, W. Riedel, H.J. Thiemich, J. Tilgner
PTB Jahresbericht 1995

Annex A Test Report Format

Notes: This Annex is **informative** with regard to the implementation of OIML R 128 in national regulations; however, use of the Test Report Format is **mandatory** for the application of the Recommendation within the OIML Certificate System.

References to the requirements of OIML R 128 are given in brackets.

A.1 Name and address of testing laboratory(ies)

.....

A.2 Reference to this Recommendation

OIML R 128, Year of edition: 20_____

A.3 Identification of the pattern to which the test report applies

For example, common and trade names and model, and a brief description including drawings, diagrams and inscriptions, specifically including the following (9.2):

- Type of ergometer and characteristics:

Patient position: Sitting up Lying down

Braking power: Controlled Uncontrolled

- Measuring range:

Power: From W To W

Rotational frequency: From min⁻¹ To min⁻¹

- Additional technical parameters:

Moment of inertia: kg·m²

Power supply: V ± %

Additional connections (e.g. input/output ports):

Accessories:

Use this space for additional information

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Note: A separate sheet may be attached if required.

A.4 Identification of samples tested (e.g. serial number)

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A.5 Name and address of manufacturer

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A.6 Name and address of applicant (if different from manufacturer)

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A.7 Dates of the test period: Start: End:

**A.8 Location and name of laboratory at which the tests were performed
(if different from the address given in A.1)**

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A.9 Information and identification

- A.9.1 List of documents submitted for the evaluation (7.1): Pass Fail
- A.9.2 Operating manual, clear and complete instructions: Pass Fail
- A.9.3 Operating manual, compliance with the requirements in clause 9: Pass Fail

A.10 Summary of tests carried out as specified in clause 7, and conditions specified in this Recommendation

A.10.1 General tests

A.10.1.1 Test for visible defects or damage: Pass Fail

A.10.1.2 Measurands and units (4): Pass Fail

Comments:

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A.10.2 Mechanical requirements (5.1)

Note: Testing for compliance with the mechanical requirements in 5.1.1 to 5.1.7 shall be carried out by measuring the distances, the angle and by visual inspection. Those in 5.1.8 shall be carried out in accordance with 7.3.4.

A.10.2.1 Adjustment of the saddle and handles without using tools (5.1.1): Pass Fail

A.10.2.2 Vertical range of the saddle position (5.1.2):

Distance \overline{CS} : mm \pm mm Pass Fail

A.10.2.3 Angle α (5.1.3): ° Pass Fail

A.10.2.4 Handle position (5.1.4):

Distance \overline{CH} : mm \pm (or radius) mm Pass Fail

A.10.2.5 Distance \overline{SH} (5.1.5): mm Pass Fail

A.10.2.6 Foot crank length L (5.1.6): mm Pass Fail

A.10.2.7 Freewheel transmission (5.1.7): Pass Fail

A.10.2.8 Moment of inertia (5.1.8): kg·m² Pass Fail

Comments:

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A.10.3 Metrological requirements for indicating devices (5.2)

Note: Testing for compliance with the requirements for the indicating device in 5.2.1, 5.2.2 and 5.2.4 to 5.2.6 shall be carried out by visual inspection, and those in 5.2.3 with a stopwatch.

A.10.3.1 Continuously indicated values (5.2.1): Pass Fail

A.10.3.2 Rotational frequency indicator visible to the patient (5.2.2): Pass Fail

A.10.3.3 Transient time or refreshing rate of indicators (5.2.3): Pass Fail

A.10.3.4 Indication of the setpoint after changing the setpoint (5.2.4): Pass Fail

A.10.3.5 Minimum scale interval or digital step (power, 5.2.5): Pass Fail

A.10.3.6 Minimum scale interval or digital step (rotational frequency, 5.2.6): Pass Fail

Comments:
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A.10.4 Metrological requirements for ergometers (5.3)

Note: Testing for compliance with the requirements for ergometers in 5.3.1 to 5.3.9 shall be carried out in accordance with 7.3.1 to 7.3.6.

A.10.4.1 Self-checking of the electronic system (5.3.1): Pass Fail

A.10.4.2 Minimum manual steps of the power setpoint (5.3.3): Pass Fail

A.10.4.3 Power control, if the rotational frequency has changed (5.3.4): Pass Fail

A.10.4.4 Power control after switching to another power setpoint (5.3.5):
Gradient of the power change: W/s Pass Fail

A.10.4.5 Power control after finishing the stressing (5.3.6):
Gradient of the power change: W/s Pass Fail

Comments:
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A.10.4.6 Error of measurements of the braking power control (5.3.2)

(Note: Maximum permissible errors (mpe's) are defined in 6.1)

a) Measurements of the absorbed braking power before warm-up phase:

Rotational frequency, min ⁻¹	70						
Power setpoint, W	25	50	75	100	150	200	250
*Absorbed braking power, W							
Maximum error W of power ≤ 60 W % in the range of power from 60 W to 250 W						

*Note: Figures entered are the mean values of at least 3 single measurements.

Ambient temperature: °C Pass Fail

Comments:

b) Measurements of the absorbed braking power after warm-up phase:

Power setpoints in W	*Absorbed braking power in W at the rotational frequency in min ⁻¹							
	40	50	60	70	80	90	100	
25								
50								
75								
100								
150								
200								
250								
300								
350								
400								
Maximum error: W of power ≤ 60 W % in the range of power from 60 W to 400 W							

*Note: Figures entered are the mean values of at least 3 single measurements.

Ambient temperature: °C Pass Fail

Comments:

A.10.4.7 Error of measurements of the indication of the rotational frequency (5.3.9)

(Note: Maximum permissible errors (mpe's) are defined in 6.2)

Rotational frequencies min ⁻¹	30	40	50	60	70	80	90	100
Ergometer min ⁻¹								
Reference min ⁻¹								
Error min ⁻¹								

Note: For ergometers with different working ranges, the table has to be modified.

Ambient temperature: °C

Pass Fail

Comments:

A.10.4.8 Continuous stress test (5.3.7)

Step No.	Power setpoints W	Rotational frequencies min ⁻¹	Absorbed braking power			
			Minimum values W	Maximum values W	Mean values W	Maximum errors %
1	50	50				
2	100	50				
3	150	60				
4	250	70				

Ambient temperature: °C

Pass Fail

Comments:

A.10.4.9 Interval test (5.3.8)

Interval No.	Power setpoints W	Rotational frequencies min ⁻¹	Absorbed braking power			
			Minimum values W	Maximum values W	Mean values W	Maximum errors %
1						
2						
3						
4						
5						
6						
7						
8						

Ambient temperature: °C

Pass Fail

Comments:

A.10.5 Technical requirements (5.4)

A.10.5.1 Sealing of the metrological functions (5.4.1):

Pass Fail

Comments:

A.10.6 Immunity (5.5)

A.10.6.1 Signal input and signal output parts (5.5.1):

Pass Fail

Note: Testing for compliance with the requirements in 5.5.1 shall be carried out in accordance with 7.3.7.

A.10.6.2 Electromagnetic compatibility (5.5.2):

Pass Fail

Note: Testing for compliance with the requirements in 5.5.2 shall be carried out in accordance with IEC 60601-1-2.

Comments:

A.11 Description of any other tests applied and their results

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A.12 Brief statement of the conclusions as to whether the sample tested meets the requirements of this Recommendation and is suitable for the designated application

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A.13 Date of test report:

Test report number:

Signature of the person(s) responsible for the test:

