DZHK-SOP-K-04

6-minute walking test (6MWT)

Version: V1.0

Effective date: 01/09/2014

Replaces version: -

Dated: -

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<th>Technical reviewer</th>
<th>Approval of Department Head</th>
<th>Approval DZHK</th>
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<td>Marcus Dörr (Greifswald) Kristin Lehner (Greifswald), adapted on the basis of SOP</td>
<td>Rolf Wachter (Göttingen)</td>
<td>Matthias Nauck</td>
<td>Thomas Eschenhagen</td>
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1 INTRODUCTION

1.1 LIST OF ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Plain text</th>
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<tr>
<td>6 MWT</td>
<td>6-minute walking test</td>
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<tr>
<td>COPD</td>
<td>Chronic obstructive pulmonary disease</td>
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<tr>
<td>O2</td>
<td>Oxygen</td>
</tr>
<tr>
<td>RPE</td>
<td>Ratings of perceived exercise</td>
</tr>
<tr>
<td>RR</td>
<td>Non-invasive blood pressure measuring using Riva-Rocci’s method</td>
</tr>
<tr>
<td>SpO2</td>
<td>Partial oxygen saturation</td>
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1.2 OBJECTIVE
This SOP describes the procedure for performing the 6-minute walking test to assess a patient’s physical fitness. It is based on the recommendations of the American Thoracic Society [1] and on the SOP of the competence network Asthma and COPD [2].

1.3 TARGET GROUP
Applies to DZHK studies and registries

1.3.1 Inclusion criteria
There are no general inclusion criteria (depending on the respective study protocol).

1.3.2 Exclusion criteria
Whenever possible, the 6-minute walking test (6MWT) should also be carried out if the subject is orthopaedically or otherwise impaired, as it provides insights about the subject’s resulting physical function and capacity in everyday life.

Absolute contraindications* for the 6-minute walking test [1] include:

- unstable angina
- myocardial infarction during the previous month

Relative contraindications include:

- resting heart rate of > 120 bpm

---
• systolic blood pressure of > 180 mmHg
• diastolic blood pressure of > 100 mmHg

Stable angina is not an absolute contraindication, but subjects with these symptoms should perform the test after taking their antianginal medication and rescue nitrate medication should be readily available.

1.4 APPLICATION AND TASKS
The 6MWT is a simple test that can be used to evaluate the functional reserves and the degree of physical tolerance of patients with chronic heart and lung diseases in their individual daily life. It is also suitable for recording the course of the disease and the success of therapeutic measures and is performed as standard both in clinic applications and in studies, especially in patients with chronic heart failure or chronic lung diseases.

1.5 QUALITY LEVEL
The 6-minute walking test always has to be performed in accordance with this SOP. This SOP corresponds to quality level 2 of the DZHK.

<table>
<thead>
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<th>DZHK quality level</th>
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<tr>
<td><strong>Performance</strong></td>
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<tr>
<td>Level 2</td>
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<tr>
<td>Level 3</td>
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</table>
### 1.6 Relationships to other examinations

The relationships between the individual SOP to other procedures are outlined below.

<table>
<thead>
<tr>
<th>Mandatory screening (SOP ...):</th>
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<td>Recommended screening (SOP ...):</td>
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<tr>
<td>Screening to be excluded (SOP ...):</td>
<td>_</td>
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<tr>
<td>Impact on other examination parts:</td>
<td>The time between this test and other physical stress tests (e.g. ergometry or cardiovascular exercise test) should not be less than 2 hours; ideally, the examination should be performed on a different day.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Mandatory follow-up (SOP ...):</th>
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<td>Follow-up to be excluded SOP:</td>
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2 PREREQUISITES OF THE EXAMINATION

2.1 REQUIREMENTS REGARDING ROOMS/EQUIPMENT
The walking path should be 30 metres long and be marked every 3 metres, whereby the start and the turning point should be marked in colour and easy to recognise (standard method). Alternatively, a measuring wheel can be used to measure the distance walked [3].

- Chair
- Telephone within easy reach
- Defibrillator within easy reach
- Possibility of oxygen supply

2.2 DEVICES/ HARDWARE
- Measuring tape to measure the length of the distance walked
- Cones to mark the turning point
- Stopwatch
- Blood pressure monitor

2.2.1 Device setup/software settings
The course is marked with the cones, the Borg scale is prepared. The Borg scale should be available as a hard copy with an adequate font size (at least 20 pt)

2.3 SPECIAL CLINICAL CONSUMABLES
- A mechanical lap counter, if required

- Alternative to marking the walking path: measuring wheel [3].

2.4 ESSENTIAL DOCUMENTS
- BORG scale as a hard copy

2.5 ESSENTIAL INFORMATION
e.g. date, patient ID, etc.
2.6 PERSONNEL

The test can be performed by a study nurse who has been trained on the SOP. The person performing the test should have basic knowledge of cardiopulmonary resuscitation or somebody with the necessary knowledge should be within calling distance while the test is being performed.

2.6.1 Training and certification

It is not intended for the examiners to be certified for this examination (training on the SOP and performance of the first examinations under the supervision of an experienced examiner is sufficient).
3 IMPLEMENTATION/WORKFLOW/WORK STEPS

3.1 FLOWCHART OF THE PROCEDURE

Preparing the subject
- No physical activity within 2 hours before the test
- Comfortable clothing
- Walking aids can be used
  In case of O2 therapy continue oxygen supply during the test

Review of contraindications

Resting phase
- Sitting down for 5 minutes
- Measure blood pressure after resting

Termination criteria
- Angina pectoris
- Severe dyspnoea
- Dizziness
- Unsafe gait, risk of falling
- Calf cramps
- Claudication
- SpO2 < 90% (if possible, repeat test after a period of rest and O2 therapy)
  SpO2 < 85% definitive termination

Start of test
- Instructions
- Demonstration
- BORG scale
- 6 minutes of walking

Follow-up
Documentation:
- Assistive devices
- Blood pressure
- Distance walked
- Special features

End of test
- BORG scale
  Measuring of the distance and calculation

Termination

Key:
- Event/task
- Observation/statement
- Leads to/continues to
- Decision
3.2 Preparing for the examination
For example, review of documents, etc.

3.2.1 Preparing the workplace
Mark the course every three metres. Mark the start and end point in colour. Alternatively, a measuring wheel can also be used.

Identify an appropriate walking distance (30-metre stretch).

3.2.2 Preparing the devices
Check the functionality of the device, e.g. calibration, software settings, etc.

3.2.3 Principles of preparing the subject for the examination
The subject must not have exercised vigorously within at least 2 hours of commencing the test. During the test, the subject should wear comfortable clothing and shoes (e.g. no shoes with high heels). During the test, subjects should continue to use their usual walking aids. Subjects who rely on continuous oxygen therapy should continue to receive oxygen during the test.

3.3 Performing the examination

Resting phase:
To begin with, instruct the subject to sit on a chair near the starting point for 5 minutes. No warm-up exercises are carried out. During the resting phase, make sure the subject is wearing appropriate clothing. In addition, once the resting phase is over, measure the systolic and diastolic blood pressure as well as the heart rate (preferably using the left arm).

Starting the test and instructing the subject:
Instruct the patient that he should walk back and forth between the two markings as fast as possible for 6 minutes. If the subject is out of breath he can slow down, stop walking and lean against the wall if necessary. He should continue walking as soon as he feels able to. Instruct the patient explicitly that the aim of the test is for him to walk as fast as possible, but that he must not run or jog and that he must not talk or allow himself to be distracted during the test.

The recommended explanations for patients are:

"The object of this test is to walk as far as possible for six minutes. You will walk back and forth in this hallway. Six minutes is a long time, but you can walk at your own pace. If you feel out of breath or become exhausted, you are permitted to slow down or stop walking. You may also lean against the wall, but you should resume walking as soon as you are able to. You will be walking back and forth in the hallway. You should pivot briskly around the mark and continue back the other way without a break. Let me show you ... Please do not
allow yourself to get distracted or talk during the test. Have you understood the instructions?"

**Demonstrating the test:**
Before starting the test, show the subject how to walk a lap.

**Performing the 6MWt:**
Once the patient signals that he is ready, the test can commence.

When the patient stands up to carry out the test, first measure his degree of dyspnoea using the **BORG Dyspnoea Scale** (see 7.1).

"Are you ready? I will count the number of laps. Remember that the purpose is to walk AS FAR AS POSSIBLE in 6 minutes; do not run or jog."

Guide the patient to the starting point. Start the timer as soon as the patient starts walking. Do not walk with the patient during the test. Encourage the patient every minute and tell him how much time is left.

"You're doing very well, you have ... minutes to go" or alternate with "Keep up the good work, you have ... minutes to go".

Do not use any other words or gestures to motivate the patient.

If the patient stops walking, say this:

"You can lean against the wall if you would like. But please continue to walk as soon as you are able to."

Tell the patient that the test will soon be over 15 seconds before the six minutes are over.

"In a moment I'm going to tell you to stop walking. I will then come to you."

End of the test: When the six minutes are over, say "Stop" loud and clearly. The examiner then walks to where the patient is standing. If the patient is very exhausted, offer him a chair to sit down on. Afterwards, reassess the degree of dyspnoea using the **BORG Dyspnoea or Exertion Scale** (see 7.1) – the type of scale to be used has to be stipulated in the respective study/the respective registry.

Measure the distance walked from the last mark in metres. Afterwards, calculate the total distance walked by adding the last measured distance in metres to the number of laps completed. [Alternatively, a measuring wheel may be used to measure the distance walked [3].]
3.4 FOLLOW-UP AND DATA COLLECTION

The following measurements and information are recorded (depending on the study / registry in the documents provided; CRF or eCRF, web form):

- Systolic and diastolic blood pressure (indicate the side on which it was measured) and heart rate prior to commencing the test after the resting phase
- Total distance walked in metres
- Value of the BORG Dyspnoea Scale before the test
- Value of the BORG Dyspnoea or Exertion Scale (see study / registry protocol) after the test
- Indication of whether assistive devices were used

Measuring wheel:

- Walking aid
- Oxygen supply during the test

If test is terminated:

- Total duration of the test
- Reason for termination

3.5 PROCEDURE IN CASE OF DEVIATIONS

Note down whether the patient used a walking aid or whether other irregularities occurred, such as breaks with leaning onto a support.

The test is terminated if any of the following symptoms occur:

- Angina pectoris
- Severe dyspnoea
- Dizziness
- Unsafe gait, risk of falling
- Calf cramps
- Claudication
- If the oxygen saturation is being measured, the test is
  - interrupted from a drop of saturation to < 90 % and repeated after a period of rest with a permanent oxygen supply of 2 litres/min.
  - stopped completely in case of a drop in oxygen saturation to less than 85 %.

4 LITERATURE AND REFERENCES


5 CHANGE

Change compared to the previous version.

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6 PERSONS INVOLVED

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<td>Dr. Kristin Lehnert</td>
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<td>PD Dr. Rolf Wächter</td>
<td>Review</td>
<td>Technical review</td>
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7 ANNEXES

7.1 BORG SCALE

The original scale that was used to assess the level of perceived exercise (RPE, ratings of perceived exercise) went from 1-20. A non-linear correlation between the perceived exercise and performance was found, so that the scale was consequently changed to a scale from 6-20, which has been tried and tested over many decades [5, 6]. In addition to this, the scale enables an approximate estimation of the respective heart rate during dynamic exercise (in healthy persons) by multiplying it by a factor of 10 (scale rating x 10 = heart rate) [5, 6].

A different, new scale ranging from 1-10 was later published. The scale is suitable for other questions such as evaluating the level of pain and isometric stress [5-7].

It is recommended to preferably use the 6/20 scale for DZHK studies. The variant of the BORG scale to be used has to be stipulated in the study protocol of the respective studies.

---

**Borg Exertion Scale**

*Subjectively perceived exertion with exercise according to Borg [5, 6]:*

| 6  | No exertion at all |
| 7  | Extremely light   |
| 8  | Very light        |
| 9  | Light             |
| 10 | Somewhat hard     |
| 11 | Hard (heavy)      |
| 12 | Very hard         |
| 13 | Extremely hard    |
| 14 | Maximal exertion  |

**Borg Dyspnoea Scale**

*Subjectively perceived dyspnoea according to Borg [4]:*

| 0  | Nothing at all   |
| 0.5| Very, very slight (just noticeable) |
| 1  | Very slight      |
| 2  | Slight           |
| 3  | Moderate         |
| 4  | Somewhat severe  |
| 5  | Severe           |
| 6  | Severe to very severe |
| 7  | Very severe      |
| 8  | Very severe to very, very severe |
| 9  | Very, very severe (almost maximal) |
| 10 | Maximal dyspnoea |
7.2 eCRF Module

6MWT

Examination details
I. Was the 6-minute walk test performed?* ○ yes □ no □ unknown □ not assessed
II. Date of examination**
   □
   □
   □ mm
   □
III. Examiner No.*
   □
IV. Quality level*
   < Bitte wählen >

1. Examination
   1.1. Measurement of blood pressure and heart rate after resting period*
       ○ yes, on left side □ yes, on right side □ no □ unknown □ not assessed
       1.1.1. Systolic blood pressure* □ mmHg
       1.1.2. Diastolic blood pressure* □ mmHg
       1.1.3. Heart rate* □ per minute
   1.2. Walk distance*
       □ m

2. Borg scale
   BORG scale (before test start)*
   2.1. Borg – dyspnoea scale* < Bitte wählen >

   BORG scale (after end of test)*
   2.2. Used BORG scale (after end of test)*
   □ Borg rating of perceived exertion scale (0/20)
   □ Borg – dyspnoea scale (0/10)
   □ unknown □ not assessed
   2.1. Borg – dyspnoea scale* < Bitte wählen >

3. Aids/stop criteria
   3.1. Were aids used? ○ yes □ no □ unknown □ not assessed
   3.1.1. If yes* ○ measuring □ walking aid □ oxygen administration ○ other □ unknown □ not assessed
   3.1.2. Please specify*

The text elements marked with the symbol ** in this SOP are binding (core data set). The text elements marked with the symbol * are to be complied with wherever possible.
6-minute walking test

3.2. Test was stopped prematurely

☐ yes ☐ no ☐ unknown ☐ not assessed

3.2.1. In case the test was stopped prematurely: Total test time

☐ mm:ss

3.2.2. Reason for stopping

☐ angina pectoris
☐ severe dyspnea
☐ dizziness
☐ insecure gait/risk of falling
☐ calf cramps
☐ claudication

☐ muscular exhaustion
☐ decreased saturation
☐ other
☐ unknown
☐ not assessed

3.2.3. Please specify

☐

3.3. Other particular findings

☐ yes ☐ no ☐ unknown ☐ not assessed

3.3.1. If yes: Examinee needs to support

☐ walking breaks
☐ examined person needs to support himself/herself
☐ other ☐ unknown ☐ not assessed

Please specify
DZHK-SOP-K-04

6-Minuten-Gehtest (6MWT)

Version: V1.0

Gültig ab: 01.09.2014

Ersetzte Version: -
Vom: -
Änderungshinweis: -

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