DZHK
DEUTSCHES ZENTRUM FÜR
HERZ-KREISLAUF-FORSCHUNG E.V.

DZHK-SOP-C-04

6-minute walking test (6MWT)

Version: V1.1 Effective date: 23.03.2023

Replaces version: V1.0 Dated: 01.09.2014

Change note: Updated eCRF

Editorial changes

This SOP is a translation from the original German SOP and valid without signatures.

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1 INTRODUCTION

1.1 LIST OF ABBREVIATIONS

Abbreviation	Plain text
6 MWT	6-minute walking test
COPD	Chronic obstructive pulmonary disease
O2	Oxygen
RPE	Ratings of perceived exercise
RR	Non-invasive blood pressure measuring using Riva-Rocci's method
SpO2	Partial oxygen saturation
WG	working group

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 register.

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, even if the subject is orthopaedically or otherwise limited, as it provides information about the subject's resulting physical function and capacity in daily living.

Absolute contraindications for the procedure [1] are*:

- unstable angina pectoris
- myocardial infarction in the past month

Relative contraindications are:

- resting heart rate of > 120 bpm
- systolic blood pressure of > 180 mmHg

- diastolic blood pressure of > 100 mmHg

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

1.4 APPLICATION AND TASKS

The 6MWT is a simple test that can be used to evaluate the functional reserves and the extent of resilience of individuals with chronic heart and lung diseases in their individual daily lives. It is also suitable for recording the course of the disease and the success of therapeutic measures and is used as standard both in clinic applications and in studies, particularly in individuals 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.

DZHK quality level	
Performance	
Level 1	The examination is performed in accordance with the guidelines of the scientific societies.
Level 2	The examination is performed in accordance with the specifications of the DZHK-SOP. Minimum requirements to ensure the quality of the implementation and the investigators are defined in the SOP.
Level 3	The examination is performed in accordance with the specifications of the DZHK-SOP and certification of the investigators: Definition of intra- and interobserver variability (standard of epidemiological studies).

1.6 RELATIONSHIPS TO OTHER INVESTIGATIONS

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

Mandatory pretest (SOP …):	_
Recommended pretest (SOP …):	_
Pretest to be excluded (SOP …):	_
Interference with other parts of the study:	The time interval to other physical stress examinations (e.g. ergometry or spiroergometry) should not be less than 2 hours; ideally, the examination should be performed on another day.

Mandatory follow-up (SOP …):	_
Recommended follow-up (SOP …):	_
Follow-up to be excluded SOP:	_

2 PREREQUISITES OF THE INVESTIGATION

2.1 REQUIREMENTS FOR ROOMS/EQUIPMENT

The course should be 30 metres long and be marked every 3 metres, with the starting point and the turning point marked in colour and clearly visible (standard method). Alternatively, a rolling tachometer can be used to measure walking distance [3].

- chair
- telephone in reachable proximity
- defibrillator in reachable proximity
- possibility of oxygen supply

2.2 EQUIPMENT/HARDWARE

- measuring tape to measure the length of the distance walked
- marks to indicate the turning point
- stopwatch
- blood pressure monitor

2.2.1 Equipment setup/software settings

Set up the course using marks, have the Borg scale ready. This should be available as a paper print out with sufficient font size (at least 20 pt)

2.3 SPECIAL CLINICAL CONSUMABLES

- a mechanical lap counter, if required
- alternative to the dimensioned track: rolling tachometer [3].

2.4 ESSENTIAL DOCUMENTS

- BORG scale as paper print out

2.5 ESSENTIAL INFORMATION

e.g. date, patient ID, etc.

2.6 STAFF

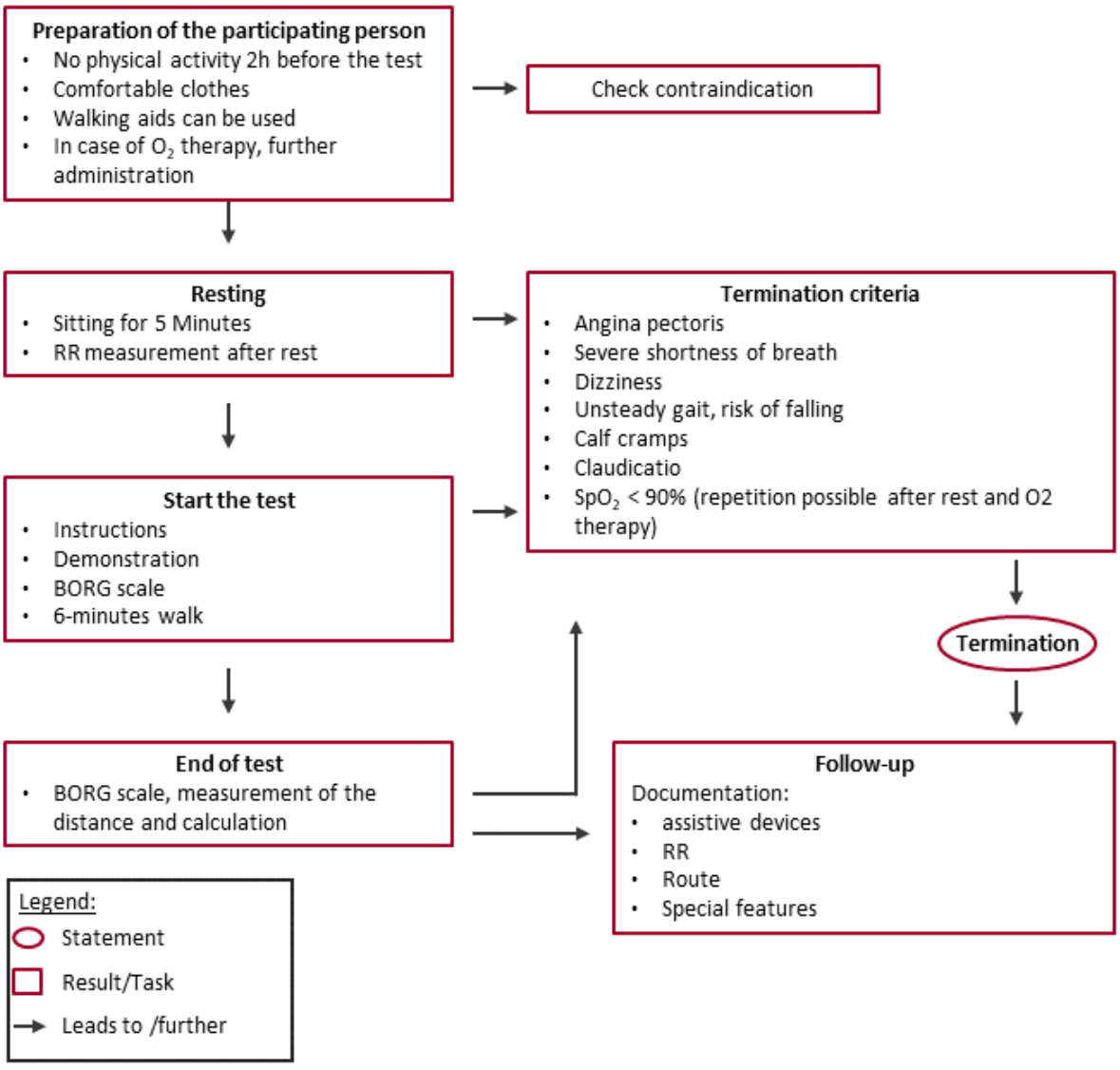
The study assistant who has been trained on the SOP, can perform the test. The person performing the test should have basic knowledge of cardiopulmonary resuscitation or somebody with appropriate knowledge should be within calling distance while the test is being performed.

2.6.1 Training and certification

Certification of the investigators is not foreseen for this investigation (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 PROCESS FLOWCHART



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 in colour. Alternatively, a rolling tachometer can also be used.

Find a suitable route (30-meter route).

3.2.2 Preparing the equipment

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

3.2.3 Principles of preparation of the person to be examined

The subject should not have performed any intense physical activity for at least 2 hours prior to the test. During the test, the person should wear comfortable clothing and shoes (e.g. no shoes with high heels). Walking aids that are also used in daily life should also be used during the test. Persons on continuous oxygen therapy should continue to receive oxygen supply during the test.

3.3 CARRYING OUT THE EXAMINATION

Resting phase:

The participating person first sits on a chair near the starting point for 5 minutes. Warm-up exercises are not performed. During the rest phase, it should be checked whether the person is wearing appropriate clothing. In addition, systolic and diastolic blood pressure, as well as heart rate, should be measured (preferably on the left arm) at the end of the rest phase. Furthermore, respiratory distress is determined according to the Borg Respiratory Distress Scale before the test begins.

The following entries are possible:

0	no shortness of breath at all
0,5	very, very mild (just perceptible)
1	very mild
2	mild
3	moderately
4	quite severe
5	heavy
6	heavy to very heavy
7	very heavy
8	very heavy to very, very heavy
9	very, very heavy (almost maximum)
10	maximum shortness of breath
unknown	
not measured	

Starting the test and instructing the participant:

The participating person is instructed to walk back and forth between the two markers as fast as possible for 6 minutes. If one gets out of breath one can slow down, stop walking and lean against the wall if necessary. One should continue walking as soon as it is possible again. It should be explicitly stated that the aim of the test is to walk as fast as possible, but not to run or jog, and not to talk or to be distracted during the test.

The recommended explanations for person taking the test are:

" You are to walk as far as you can in this test within six minutes. To do so, 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 turn quickly around the mark and continue without pausing. Let me show you ... During the test, please do not be distracted or speak. Do you understand everything?"

Demonstrating the test:

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

Performing the 6MWT:

Once the participating person signals to be ready, the test can begin.

When the patient stands up to carry out the test, first measure the degree of respiratory distress using the **BORG Respiratory Distress Scale** (see 7.1)

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

Guide the participant to the starting point. Once the person has started walking, the stopwatch is started. The person is not accompanied while walking, but encouraged every minute, and the remaining time is announced.

"You're doing very well, you have ... minutes to go" or alternately with "Keep going, you still have ... minutes to go".

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

If the participant stops walking, you may say the following:

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

15 seconds before the end of the six minutes, the participant is told that the test is about to end. "In a moment I will aks you to stop walking. I will join you then."

End of the test: When the six minutes are over, say "Stop" loud and clear. The examiner goes to the participant. If the person is very exhausted, a chair can be offered. Respiratory distress is then recorded again using the Borg Respiratory Distress or Effort Scale (see 7.1) – which scale to use must be defined in the respective study/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 rolling tachometer may be used to measure the distance walked [3].]

3.4 FOLLOW-UP AND DATA COLLECTION

The following measurements and information will be 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 performing the test after resting
- total distance walked in metres
- value of the BORG Respiratory Distress before the test
- value of the BORG Respiratory Distress or Exertion Scale (see study / registry protocol) after the test
- information if assistive devices were used
- rolling tachometer
- walking aid
- oxygen supply during the test
- other
- not collected
- unknown

In case of termination:

- total duration of the test
- reason for termination

3.5 DEALING WITH DEVIATIONS

Note down whether the patient used a walking aid or whether other abnormalities occurred, such as pauses with bracing.

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

- angina pectoris

- severe shortness of breath
- dizziness
- unsafe gait, risk of falling
- calf cramps
- claudication
- muscular fatigue
- drop in satiety
- from the test is stopped at a drop in saturation < 90 % and repeated after a period of rest under permanent oxygen administration of 2 liters/min. If oxygen saturation drops below 85%, the test is definitely stopped.
- other
- unknown
- not collected

4 LITERATURE AND REFERENCES

1. ATS statement: guidelines for the six-minute walk test. American journal of respiratory and critical care medicine, 2002. 166(1): p. 111-7.
2. Kompetenznetz Asthma und COPD. SOP 6-Minuten Gehtest. Available from: http://www-mhh.asconet.net
3. Haass, M., C. Zugck, and W. Kübler, Der 6-Minuten-Gehtest: Eine kostengünstige Alternative zur Spiroergometrie bei Patienten mit chronischer Herzinsuffizienz? [The 6 minute walk test: A cost effective alternative to cardiopulmonary exercise testing in patients with congestive heart failure?]. Z Kardiol 2000. 89: p. 72-80.
4. Borg, G.A., Psychophysical bases of perceived exertion. Medicine and science in sports and exercise, 1982. 14(5): p. 377-81.
5. Borg, G., Anstrengungsempfinden und körperliche Aktivität. Dtsch Arztebl International, 2004. 101(15): p. 1016-.
6. Löllgen, H., Das Anstrengungsempfinden (RPE, Borg-Skala). Deutsche Zeitschrift für Sportmedizin, 2004. 55(11): p. 299-300.
7. Borg, G.A., Borg's perceived exertion and pain scales in Human Kinetics, Champaign Il. 1998

5 CHANGE

Change compared to the previous version.

Section	Description of the change to the previous version
7.2	Updated eCRF

6 PERSONS INVOLVED

Name	Role	Involvement
Prof. Dr. Marcus Dörr	Initial author	Author
Dr. Kristin Lehnert	Author	Author
PD Dr. Rolf Wachter	Review	Expert review
Dr. Natalie Arnold	WG Data standardization	Scientific review
Prof. Marcus Dörr	WG Data standardization	Scientific review
Prof. Frank Edelmann	WG Data standardization	Scientific review
Dr. Christoph Gertler	WG Data standardization	Scientific review
Prof. Stefan Kääb	WG Data standardization	Scientific review
Prof. Till Keller	WG Data standardization	Scientific review
Dr. Monika Kraus	WG Data standardization	Scientific review
Dr. Kristin Lehnert	WG Data standardization	Scientific review
Prof. Benjamin Meder	WG Data standardization	Scientific review
Prof. Eike Nagel	WG Data standardization	Scientific review
Prof. Matthias Nauck	WG Data standardization	Scientific review
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Dr. Johannis Trebing	WG Data standardization	Scientific review
Prof. Philipp Wild	WG Data standardization	Scientific review
Prof. Tanja Zeller	WG Data standardization	Scientific review
Mahsa Lee	WG Data standardization	IT implementation
Dipl.-Inf. Sabine Hanß	WG Data standardization	IT implementation
Dr. Julia Hoffmann, Dr. Ilka Wilhelmi	WG Data standardization	Coordination

7 APPENDIX

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]:

(Borg-RPE scale, RPE = ratings of perceived exercise)

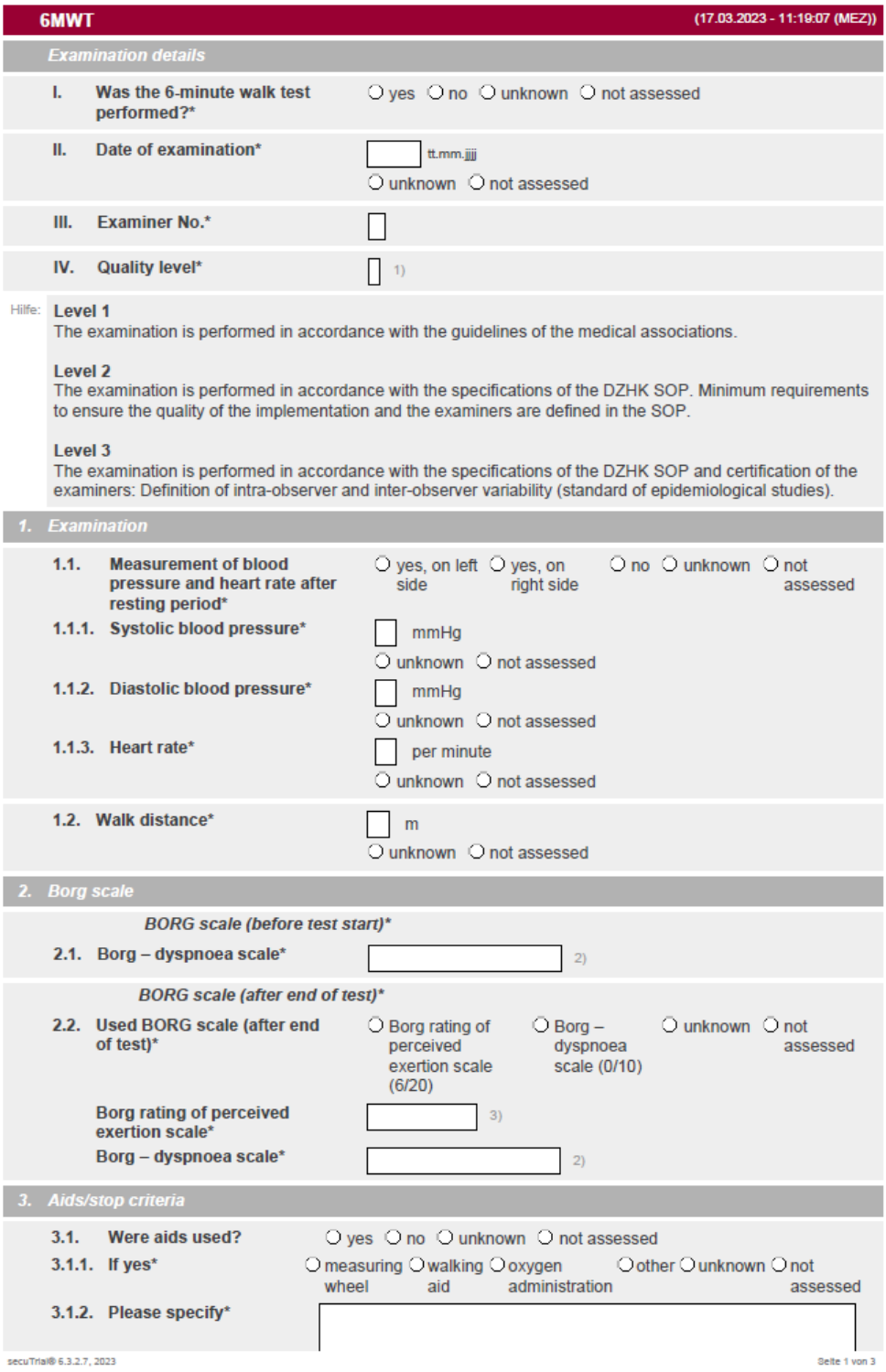
6	No exertion at all
7	Extremely light
8	
9	Very light
10	
11	Light
12	
13	Somewhat hard
14	
15	Hard (heavy)
16	
17	Very hard
18	
19	Extremely hard
20	Maximal exertion

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 (17.03.2023 - 11:19:07 (MEZ))

Examination details

I. **Was the 6-minute walk test performed?*** ○ yes ○ no ○ unknown ○ not assessed

II. **Date of examination*** [ ] tt.mm.jjjj ○ unknown ○ not assessed

III. **Examiner No.*** [ ]

IV. **Quality level*** [ ] 1)

Hilfe:

Level 1
The examination is performed in accordance with the guidelines of the medical associations.

Level 2
The examination is performed in accordance with the specifications of the DZHK SOP. Minimum requirements to ensure the quality of the implementation and the examiners are defined in the SOP.

Level 3
The examination is performed in accordance with the specifications of the DZHK SOP and certification of the examiners: Definition of intra-observer and inter-observer variability (standard of epidemiological studies).

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 ○ unknown ○ not assessed

1.1.2. **Diastolic blood pressure*** [ ] mmHg ○ unknown ○ not assessed

1.1.3. **Heart rate*** [ ] per minute ○ unknown ○ not assessed

1.2. **Walk distance*** [ ] m ○ unknown ○ not assessed

2. Borg scale

BORG scale (before test start)*

2.1. **Borg – dyspnoea scale*** [ ] 2)

BORG scale (after end of test)*

2.2. **Used BORG scale (after end of test)*** ○ Borg rating of perceived exertion scale (6/20) ○ Borg – dyspnoea scale (0/10) ○ unknown ○ not assessed

Borg rating of perceived exertion scale* [ ] 3)

Borg – dyspnoea scale* [ ] 2)

3. Aids/stop criteria

3.1. **Were aids used?** ○ yes ○ no ○ unknown ○ not assessed

3.1.1. **If yes*** ○ measuring wheel ○ walking aid ○ oxygen administration ○ other ○ unknown ○ not assessed

3.1.2. **Please specify*** [ ]

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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 ○ unknown ○ not assessed
3.2.2.	**Reason for stopping***	○ angina pectoris ○ severe dyspnoea ○ 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***	○ walking breaks ○ examined person needs to support himself/herself ○ other ○ unknown ○ not assessed
	Please specify*	

Mögliche Angaben

Bitte wählen Sie bei den oben mit Anmerkungen versehenen Feldern eine der hier aufgelisteten Angaben.

1) 1

2
3

2)

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

3)

6 - No exertion at all
7 - Extremely light
8
9 - Very light
10
11 - Light
12
13 - Somewhat hard
14
15 - Hard (heavy)
16
17 - Very hard
18
19 - Extremely hard
20 - Maximal exertion
unknown
not assessed