DZHK-SOP-C-07
Cardiopulmonary exercise test (spiroergometry)

Version: V1.2                            Effective date: 21.06.2023

Replaces version: 1.1                        Dated: 01.07.2015

Change note: Definition of the load limit
Supplementary information on treadmill protocols
Adaptation of the eCRF

This SOP is a translation from the original German SOP and valid without signatures. Printouts are not updated!
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1 INTRODUCTION

1.1 LIST OF ABBREVIATIONS
The following values are measured during the test and explained in the table below.

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<th>Abbreviation</th>
<th>Unit</th>
<th>Explanation</th>
<th>Standard parameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>[AT]</td>
<td></td>
<td>[Anaerobic threshold, equivalent to VT1]</td>
<td></td>
</tr>
<tr>
<td>BE</td>
<td></td>
<td>Base excess</td>
<td></td>
</tr>
<tr>
<td>BF</td>
<td>l/min</td>
<td>Breathing frequency</td>
<td>*</td>
</tr>
<tr>
<td>BGA</td>
<td></td>
<td>Blood gas analysis</td>
<td></td>
</tr>
<tr>
<td>ECG/EKG</td>
<td></td>
<td>Electrocardiogram</td>
<td></td>
</tr>
<tr>
<td>EQ CO₂</td>
<td></td>
<td>Ventilatory equivalent for CO₂, corresponds to VE/VCO₂</td>
<td></td>
</tr>
<tr>
<td>EQO₂</td>
<td></td>
<td>Ventilatory equivalent for O₂, corresponds to VE/VO₂</td>
<td></td>
</tr>
<tr>
<td>HCO₃</td>
<td></td>
<td>Bicarbonate</td>
<td></td>
</tr>
<tr>
<td>HR (exercise)</td>
<td>Beats per minute (bpm)</td>
<td>Heart rate at maximum exercise [highest value during exercise]</td>
<td>*</td>
</tr>
<tr>
<td>HR (resting)</td>
<td>Beats per minute (bpm)</td>
<td>Heart rate at rest [last value of the resting phase]</td>
<td>*</td>
</tr>
<tr>
<td>HRR</td>
<td>bpm or %</td>
<td>Heart rate reserve, as the difference between the calculated maximum heart rate (200 – age in years) and the maximum heart rate achieved – absolute or as a percentage</td>
<td></td>
</tr>
<tr>
<td>MVV</td>
<td>l</td>
<td>Maximum voluntary ventilation as a calculated value (FEV1 x 41)</td>
<td></td>
</tr>
<tr>
<td>O₂/HR</td>
<td>ml/heartbeat</td>
<td>Oxygen pulse, expressed as a ratio between oxygen uptake and heart rate</td>
<td></td>
</tr>
<tr>
<td>PET CO₂ (exercise)</td>
<td>mmHg</td>
<td>Maximum value of the end-tidal CO₂ partial pressure</td>
<td>*</td>
</tr>
<tr>
<td>PET CO₂ (resting)</td>
<td>mmHg</td>
<td>End-tidal CO₂ partial pressure (at the end of exhaling) at rest [averaged across 3 minutes of resting]</td>
<td>*</td>
</tr>
<tr>
<td>PET CO₂-AT</td>
<td>mmHg</td>
<td>End-tidal CO₂ partial pressure at the aerobic/anaerobic threshold</td>
<td></td>
</tr>
<tr>
<td>PET O₂-AT</td>
<td>mmHg</td>
<td>O₂ partial pressure at the aerobic/anaerobic threshold</td>
<td></td>
</tr>
<tr>
<td>PET O₂-max</td>
<td>mmHg</td>
<td>Maximum value of O₂ partial pressure</td>
<td></td>
</tr>
</tbody>
</table>
### Abbreviation

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Unit</th>
<th>Explanation</th>
<th>Standard parameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>PET O₂ (resting)</td>
<td>mmHg</td>
<td>End-tidal O₂ partial pressure at rest</td>
<td></td>
</tr>
<tr>
<td>[RCP]</td>
<td></td>
<td>[Respiratory compensation point, corresponds to VT 2 (see 1.5)]</td>
<td></td>
</tr>
<tr>
<td>RER</td>
<td></td>
<td>Respiratory exchange ratio, corresponds to RQ</td>
<td></td>
</tr>
<tr>
<td>RQ (exercise)</td>
<td></td>
<td>Respiratory quotient at the end of exercise, corresponds to RER during exercise</td>
<td>*</td>
</tr>
<tr>
<td>RQ (resting)</td>
<td></td>
<td>Respiratory quotient at rest, corresponds to RER at rest</td>
<td>*</td>
</tr>
<tr>
<td>RQ maxpost</td>
<td></td>
<td>Maximum respiratory quotient post-exercise, corresponds to the max. RER post-exercise</td>
<td></td>
</tr>
<tr>
<td>RR</td>
<td></td>
<td>Manual blood pressure measurement</td>
<td></td>
</tr>
<tr>
<td>RRsyst (exercise)</td>
<td>mmHg</td>
<td>Systolic blood pressure at the end of exercise</td>
<td>*</td>
</tr>
<tr>
<td>RRsyst (resting)</td>
<td>mmHg</td>
<td>Systolic blood pressure at rest</td>
<td>*</td>
</tr>
<tr>
<td>RRsys</td>
<td></td>
<td>Diastolic blood pressure at the end of exercise</td>
<td></td>
</tr>
<tr>
<td>RRdia (resting)</td>
<td>mmHg</td>
<td>Diastolic blood pressure at rest</td>
<td>*</td>
</tr>
<tr>
<td>RRdia (exercise)</td>
<td>mmHg</td>
<td>Diastolic blood pressure at the end of exercise</td>
<td></td>
</tr>
<tr>
<td>SO₂ (exercise)</td>
<td>%</td>
<td>Peripheral oxygen saturation at the end of exercise</td>
<td>*</td>
</tr>
<tr>
<td>SO₂ (resting)</td>
<td>%</td>
<td>Peripheral oxygen saturation at rest</td>
<td>*</td>
</tr>
<tr>
<td>VE max</td>
<td>l/min</td>
<td>Maximum respiratory minute volume, measured during exhalation</td>
<td>*</td>
</tr>
<tr>
<td>VE max./MVV</td>
<td>%</td>
<td>Maximum achieved ventilation in relation to MVV</td>
<td></td>
</tr>
<tr>
<td>VE/VCO₂ (resting)</td>
<td></td>
<td>Respiratory equivalent for CO₂ (volume of inhaled air to emit one litre of CO₂) at rest, corresponds to Eq CO₂ [averaged across 3 minutes of resting]</td>
<td>*</td>
</tr>
<tr>
<td>VE/VCO₂-AT</td>
<td></td>
<td>Respiratory equivalent for CO₂ at the aerobic/anaerobic threshold</td>
<td></td>
</tr>
<tr>
<td>VE/VCO₂ slope</td>
<td></td>
<td>Increase (slope) of the ventilation-CO₂ ratio [determination via the slope (1 min. after starting exercise until RCP)]</td>
<td>*</td>
</tr>
<tr>
<td>VE/VO₂ (resting)</td>
<td></td>
<td>Respiratory equivalent for O₂ (volume of inhaled air to absorb one litre of O₂), corresponds to Eq O₂ [averaged across 3 minutes of resting]</td>
<td>*</td>
</tr>
<tr>
<td>VE/VO₂-AT</td>
<td></td>
<td>Respiratory equivalent for O₂ at the aerobic/anaerobic threshold</td>
<td></td>
</tr>
<tr>
<td>VO₂ (AT)</td>
<td>ml/min</td>
<td>O₂ uptake at the aerobic/anaerobic threshold</td>
<td>*</td>
</tr>
<tr>
<td>VO₂ (normal)</td>
<td>ml/min</td>
<td>See section 8.2 for reference values</td>
<td>*</td>
</tr>
</tbody>
</table>
### Abbreviation Table

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Unit</th>
<th>Explanation</th>
<th>Standard parameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>VO₂ (resting)</td>
<td>ml/min</td>
<td>O₂ uptake at rest [averaged across a resting phase]</td>
<td>*</td>
</tr>
<tr>
<td>VO₂ peak</td>
<td>ml/min</td>
<td>Peak O₂ uptake at the end of exercise [highest quantifiable value during exercise]</td>
<td>*</td>
</tr>
<tr>
<td>VO₂ peak/kg</td>
<td>ml/min/kg</td>
<td>Peak O₂ uptake per kilogram of bodyweight¹</td>
<td></td>
</tr>
<tr>
<td>VO₂-AT/kg</td>
<td>ml/min/kg</td>
<td>O₂ uptake at the aerobic/anaerobic threshold per kilogram of bodyweight</td>
<td></td>
</tr>
<tr>
<td>VO₂/Watt</td>
<td>ml/Watt</td>
<td>Aerobic capacity</td>
<td></td>
</tr>
<tr>
<td>VT</td>
<td>L</td>
<td>Tidal volume</td>
<td></td>
</tr>
<tr>
<td>VT1</td>
<td></td>
<td>first ventilatory threshold, former AT</td>
<td></td>
</tr>
<tr>
<td>VT2</td>
<td></td>
<td>equals respiratory compensation point (RCP)</td>
<td></td>
</tr>
</tbody>
</table>

¹ Averaging of the respiratory gas analyses across 30 seconds
1.2 **OBJECTIVE**
Spiroergometry is used to assess general physical performance and endurance. For this purpose, a differentiated observation of the function of the cardiovascular, pulmonary and peripheral-muscular system is carried out at rest and at different timepoints during physical exercise. Important parameters in this observation are values of gas exchange (oxygen uptake at the anaerobic threshold and at maximum load, ratio of oxygen uptake and carbon dioxide release), of cardiovascular function (heart rate and blood pressure curves, ECG changes), of ventilation (determination of the respiratory minute volume, of the breathing pattern, of the coupling of gas exchange and ventilation, so-called breathing equivalents).

1.3 **TARGET GROUP**
The SOP shall be applied in all interventional studies and registries in the DZHK.

1.3.1 **Inclusion criteria**
All persons who are capable of cycling on an ergometer or of doing exercise on a treadmill and to whom no exclusion criteria apply may participate. Special inclusion criteria can be found in the study protocol of the respective study/registry.

1.3.2 **Exclusion criteria**
**Absolute contraindications:**
- acute relevant disease, e.g. recent myocardial infarction, systemic infections, thromboses or embolisms, acute exacerbation of a respiratory disease
- severe cardiac arrhythmias or block formation (AV block of II or III degree)
- insufficiently controlled arterial hypertension (RRsyst >170 mmHg, and/or RRdiast >110 mmHg)
- known symptomatic or severe aortic stenosis

**Relative contraindications:**
- resting tachycardia (>120 bpm)
- poorly controlled epilepsy with risk of seizure provocation by exercise
- symptomatic electrolyte disturbance or metabolic imbalance
- symptomatic cerebral circulatory disturbance

If necessary, specific criteria of the respective studies or registries have to be observed.

1.4 **APPLICATION AND TASKS**
Spiroergometry is a diagnostic procedure that qualitatively and quantitatively analyses the reactions and interactions of the heart, circulation, respiration and metabolism during gradually increasing
exercise. Three measurement signals are recorded by a breathing mask: the oxygen fraction of exhaled air, the carbon dioxide fraction of exhaled air and the volume of exhaled air. Together with the recorded heart rate and blood pressure, further meaningful parameters can be calculated from these variables. Modern devices are programmed to measure these variables with every breath (breath-by-breath analysis) using rapid analyzers and to numerically record and graphically process the results online using corresponding software.

1.5 Terms and Definitions

**Anaerobic threshold determined by ventilation (AT or VT1):** Defines the first increase in lactate and represents the beginning of the aerobic/anaerobic transition. This value can be determined via the first change in the slope in field 5 of the Wassermann graphs (see, for example, Meyer FJ and Preßler A. Stress testing - spiroergometry in DGIM Innere Medizin, Springer-Verlag 2018) (VCO₂/VE) or via the first increase in the oxygen equivalent in field 6 of the Wassermann graphs (EQO₂).

**VE/VCO₂ slope:** Defined as the slope of the straight line in field 5 (VE to VCO₂) value one minute after starting the exercise until VT2 (RCP).

**Respiratory compensation point (RCP or VT2):** Defined as the point at which there is a disproportionate increase from VE to VCO₂, read as an increase in EQCO₂ in field 6.

1.6 Relationships to other examinations

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

<table>
<thead>
<tr>
<th>Mandatory preliminary examination (SOP ...):</th>
<th>Pulmonary function analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommended preliminary examination (SOP ...):</td>
<td>Examination at rest</td>
</tr>
<tr>
<td>Preliminary examination to be excluded (SOP ...):</td>
<td>Other exercise test</td>
</tr>
<tr>
<td>Impairment of other examination parts:</td>
<td>Other (exercise) tests</td>
</tr>
<tr>
<td>Mandatory follow-up (SOP ...):</td>
<td>Does not apply</td>
</tr>
<tr>
<td>Recommended follow-up (SOP ...):</td>
<td>Spiroergometry should be the last examination performed on the examination day</td>
</tr>
<tr>
<td>Follow-up to be excluded (SOP ...):</td>
<td>Echocardiography</td>
</tr>
</tbody>
</table>

The text elements highlighted in gray in this SOP are mandatory (= basic data set). The text elements that are not highlighted must be adhered to if possible.
### 1.7 Quality Level

**DZHK quality level**

<table>
<thead>
<tr>
<th>Performance</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>The examination is performed in accordance with the guidelines of the scientific societies.</td>
</tr>
<tr>
<td>Level 2</td>
<td>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.</td>
</tr>
<tr>
<td>Level 3</td>
<td>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).</td>
</tr>
</tbody>
</table>

This SOP describes level 2.
2 PREREQUISITIES OF THE EXAMINATION

2.1 REQUIREMENTS REGARDING ROOMS/EQUIPMENT

Requirements regarding rooms

Recommended for all spiroergometry facilities:

- recommended temperature: 22°C (range 20-26°C) stable during the day, with as little ventilation as possible
- room temperature: is measured and adjusted automatically (+18 - +34°C)
- humidity: is measured and adjusted automatically
- brightness: no requirements
- air pressure: is measured and adjusted automatically
- no passage room, if possible washing facilities/shower for participating persons

Room equipment

- laptop for data entry
- color printer for printing the findings sheet
- desk with an office chair
- desk lamp
- telephone
- chair for participant
- body plethysmograph or spirometry (optional, sufficient if available in close proximity)
- blood gas analyzer
- ergometer
- spiroergometry workstation (complete)
- examination couch
- emergency case
- defibrillator
- blood pressure monitor for manual control
- BORG scale (6-20 or 0-10)
- gloves, consumables (including disinfectant wipes, gauze compresses, plasters)

2.2 DEVICES/HARDWARE

2.2.1 Device name and description

Center specific.

2.2.2 Calibration

It is important, among others, to perform calibrations using calibration gases (once per workday) according to the manufacturer's instructions.
In addition, volume calibration has to be performed on the device (after every examination).

Instrument calibration/verification is done daily before the start of the examination and includes the following components (performed according to the instrument-specific instructions):

- instrument calibration
- volume calibration

Volume calibration is carried out in the morning after the calibration and after each examination. As a result of the calibration, the computer calculates the correction factors.

The results of calibration and volume calibration are stored in the instrument.

- Gas analyzer calibration

**Biological calibration**

Every 12 months, the same person should perform an examination on the same spiroergometer to verify the plausibility of the entire system (especially if O2 electrodes with a time limitation are used).

**If the room temperature changes by more than 5°C during the day, a new calibration has to be performed.**

**2.2.3 Sources of error**

- **Automatic blood pressure measurement:**
  
  With increasing load, there are more upper body movements of the participating persons, which can lead to incorrect measurements of the sensors due to movement. If implausible values occur, a second measurement should be done manually.

- **ECG:**
  
  Movement and transpiration can cause detachment of electrodes. In this case, the electrode should be reattached or replaced (exchanged).

- **Breathing mask:**
  
  Lack of contact of the breathing mask with the skin (e.g. small face, beard, talking, grimacing) can cause leaks that lead to incorrect breathing gas determination. Therefore, the correct fit of the mask should be checked prior to the examination and a different mask tried out if necessary. The participant should be instructed to speak only in case of emergency after the breathing mask has been fitted and to indicate a desired termination of the examination by means of a hand signal towards the examiner. The sample tubes located on the turbine should always point at least 45° upwards.

- **Adjusting the seat height on the bike:**
  
  This has to be adjusted specifically for the participant prior to each examination to ensure an optimal transmission of force. Sufficient fastening of sturdy footwear to the pedals is mandatory.
2.2.4 Wear-spare parts

Masks:
- There should be 2-3 masks in varying sizes (children's mask, small, medium, large). The masks can be used as long as they are working correctly. The Velcro straps for fitting the masks have to be replaced as soon as sufficient closure for correct positioning of the mask is no longer given.

Sensors:
- A defective sensor may be the cause of a calibration error.

Condensate tube:
- The condensate tube should be replaced whenever the computer system displays a corresponding alert.

ECG suction electrodes:
- Replace only in case of a defect (decision by the medical technical staff).

2.2.5 Storage
No special requirements.

2.2.6 Maintenance/ device care

Clean and disinfect the device (ear clip, blood pressure cuff, ECG suction electrodes and cycle) with Cleanisept wipes after each use.

Maintenance is performed in accordance with EN 62353.
2.3 **SPECIAL CLINICAL CONSUMABLES**

*Prepare the following items for the examination:*

- 1 skin disinfectant spray,
- 1 pair of gloves,
- 3 lancets (optional),
- glass capillaries, if possible with lid systems (optional for ABG and/or lactate measurement),
- magnets (mixing wires) (optional for HSM, ICD deactivation),
- compresses,
- 1 small plaster,
- contact spray for ECG electrodes,
- Elacur ointment (optional)

2.4 **ESSENTIAL DOCUMENTS**

Information, informed consent, other clinical documents (see below).

2.5 **ESSENTIAL INFORMATION**

The correct choice of the testing program, complete information about the participating person, patient ID.

2.6 **STAFF**

The staff must have had special training and certification at the examination center (see section 6).

1 performing examiner (certified nursing staff or MTA).

1 assisting examiner (certified nursing staff or MTA) (if BGA collection is planned).

1 medical examiner on call to monitor and evaluate the examination.

Staff must be trained on general emergencies and resuscitation.

Training of examining staff

Newly trained staff should accompany an experienced during 5 spiroergometries performed according to this DZHK-SOP-C-07, and then independently carry out at least 20 spiroergometries under supervision, and also complete the regular certification sessions of level 2/3.
3 IMPLEMENTATION/WORKFLOW/WORK STEPS

3.1 FLOWCHART OF THE PROCEDURE

- Daily before start of examination
  - calibration of the system

- Preparation of the workplace
  - input of patient ID

- Conducting the examination
  - short explanation of examination
  - attachment of 12-channel ECG
  - application of automatic blood pressure cuff
  - attachment of pulse oximeter
  - attachment of respiratory mask
  - checking respiratory mask for leakage
  - preparation of blood gas analysis (optional)

- Measurement and data collection
  - depending on the protocol used, here the modified Jones protocol as an example:
  - BGA from hyperemic earlobe from lung function (optional)
  - rest (3 min of relaxed sitting on the ergometer):
    → automatic RR measurement, manual control if necessary
    → if necessary, perform the intrabreath maneuver (after 1 min)
  - exercise (start 20 Watt, increase 10 W/min):
    - person begins to pedal, > 50 rotations should be reached
    → automatic RR measurement every minute, if necessary manual control
    - optional in the range of AT
      → BGA
      → intrabreath maneuver
    - optional at the end of exercise
      → BGA
      → intrabreath maneuver
  - recovery/post load at 20 Watt:
    → automatic RR measurement, manual control if necessary
    → monitoring until resting RR is reached
    → removal of respiratory mask after 2 minutes

- Reasons to terminate the examination
  - ST-segment depression (> 0.2 mV) or elevation
  - progressive atrial or ventricular arrhythmias or block patterns
  - new onset of atrial fibrillation
  - drop of frequency during exercise
  - missing rise of RR or drop of RR over two levels of exercise load
  - drop in O₂ uptake (or oxygen pulse) despite increase in exercise load
  - maximum exhaustion (e.g., of the legs)
  - chest pain (e.g., AP symptoms), severe dizziness
  - excessive dyspnea
  - person indicates desire to stop

- Follow-up
  - survey of the BORG scale (20)
  - survey of any existing clinical complaints
  - survey of the reason for termination
  - (handing out towel and/or drinks)

Follow-up discussion
- information about the technical quality of the examination by the examining staff
- orienting assessment of the performance by the examining staff

Explanation:
- Decision
- Event/task
- Leads to/continues

Termination
3.2 PREPARING FOR THE EXAMINATION

3.2.1 Verification the informed consent form
In the context of studies, the in- and exclusion criteria are already described in the study information; so that all participants who give their consent can perform the examination. In the context of a clinical application, it is necessary to clarify whether there are contraindications to the performance of spiroergometry by means of a medical history or available doctor’s letters and questioning of the participating person.

3.2.2 Identification of the participant
The identity of a participating person is clarified by querying name and date of birth. In the context of studies, a patient ID is entered into the software.

3.2.3 Checking inclusion criteria

3.2.4 Check whether consent for study participation has been obtained. Preparing the workplace
Disinfect the mentioned materials and equipment parts listed. Reach a comfortable room temperature, ventilate if necessary.

3.2.5 Preparing the devices
Preparation according to the device-specific instructions. Averaging of the respiratory gas analysis should take place over 10 seconds during the examination to ensure the monitoring of the patient and to enable the BGA sampling (optional) can be taken as close as possible within the range of the anaerobic threshold.

3.2.6 Preparing the participant for the examination
Explanations, instructions for participant

* Spiroergometry:

- the ECG, blood pressure cuff, saturation clip and the breathing mask are now applied
- the breathing mask will be connected to a sensor that measures the respiratory gases. Do not speak after the sensor has been connected
- you must now sit quietly for 3 minutes* to record resting respiratory, blood pressure and ECG
- at the beginning you will start the examination with a load of 20 watts*, which will be increased by 16 watts* every minute. Please try to maintain 55-65 rotations when pedaling. [Note: example modified Jones protocol]
- at rest, during the exercise and just before the end of the exercise, I will ask you to take one deep breath and then to continue breathing normally; this is to record the intrabreath maneuver (optional, defined in the respective study protocol).
- the examination will be terminated by you, unless irregularities occur beforehand that result in the examination to be terminated. Please give us a signal with your hand when you want to

---

* The value depends in each case on the load protocol used (chapter 8.2)
end the examination. Please continue pedaling after your hand signal; I will decrease the load again to allow you to recover slowly at 20 watts.

- Immediately after ending the examination please use your fingers to rate your level of exertion using the BORG scale (6-20 or 0-10 depending on the requirements of the respective study protocol) which I am showing to you here. You must not speak yet.

- Do you have any questions?

**Blood gas analysis (optional):**

- During the examination, a colleague will assist me and will collect two samples of blood from your earlobe.

### 3.3 CARRYING OUT THE EXAMINATION

#### 3.3.1 Exercise protocol

In principle, spiroergometry can be performed according to different exercise protocols that should be selected depending on the target population [2].

The respective study/registry protocol must define which protocol is to be used. A selection of cycling and treadmill protocols is provided in the appendix (see 8.2)

#### 3.3.2 Preparing the participant, measuring position

- correct application of the 12-lead ECG
- correct application of the breathing mask and checking for leaks
- correct application of the blood pressure cuff
- correct application of the saturation sensor
- for cycle ergometers additionally:
  - adjustment of seat height and handlebar on the ergometer
  - attaching the Velcro fasteners of the pedals to the foot of the participating person
- for treadmills additionally:
  - attaching the safety belt/auto-stop
### 3.3.3 Performing the stress test

Values measured at rest:

- first perform spirometry at rest to rule out significant lung disease (Tiffeneau’s test); alternatively: pulmonary function testing prior to spiroergometry testing (spirometry, body plethysmography)
- then record the gas exchange for 3 minutes at rest
- start the exercise test if RER is < 1. If the RER is > 1 after 3 minutes at rest and still after another 3 minutes (total 6 min), the test should still be started
- measure the RR before starting the exercise phase. Prior to starting the exercise, the RR should not exceed 170/110 mmHg

### 3.3.4 Exercise phase:

- The speed will be constant at 55-65 rpm (bicycle ergometry) for the duration of the test. While the speed (cadence) remains constant, the resistance is gradually increased according to the exercise protocol. At the end of each stage, HR and RR are measured and noted
- the participants should be strongly encouraged to continue the exercise as long as possible (observing the termination criteria, see below)
- optional: if the RER is 0.9, preparation for the BGA should be started at the AT so that the blood sample can be collected before RER 1
- optional: the BGA at the end of the exercise is done if the participant indicates to end the test immediately, or if the examiner has the impression that the participant will stop the test soon (severe exhaustion, drop in cadence, etc.) or if reasons for termination are present
- the test should be continued until the participant meets subjective or objective termination criteria that justify terminating the test

**Objective termination criteria are:**

- ST-segment depression (> 0.2 mV) or elevation
- progressive atrial or ventricular arrhythmia or block images
- new onset atrial fibrillation
- rate decrease during exercise
- absence of rise or drop in RR across 2 levels of exercise
- drop in O\textsubscript{2} uptake (or oxygen pulse) despite increase in load

**Subjective termination criteria are:**

- maximal exhaustion (e.g. of the legs)
- chest pain (e.g. AP symptoms), severe dizziness
- excessive dyspnea
- participant indicates desire to discontinue
3.3.5 Recovery phase:
- the participant keeps the mask on
- immediately after the end of the exercise, the BORG scale is queried by means of hand signal
- the participant should continue pedaling without resistance for 2 minutes. After 2 more minutes, the participant should stop pedaling
- the mask should be removed at the earliest 2 minutes after starting the recovery phase
- continue the ECG, HR and RR measurements for at least 6 minutes in 2-minute intervals. Continue the RR measurements until the blood pressure returns to baseline
- during the recovery phase, it is known that individuals may have a sharp drop in RR. Therefore, the participant should be asked regularly about dizziness and malaise. If dizziness/extreme pallor occur, or if the participant responds inadequately, the examination must be discontinued

3.3.6 Documentation:
- all relevant data will be documented in the eCRF after completing the examination

3.4 FOLLOW-UP AND DATA COLLECTION
Post processing of the examination
The spiroergometry equipment is cleaned with Cleanisept Wipes®. The mask and sensor are disinfected as described in section 1.3.2.

3.4.1 Biomaterial
As an optional analysis, one capillary of blood is collected from the earlobe hyperemized with ELACUR hot 2.0 % (Riemser®) at rest, in the anaerobic threshold region and at maximum load.

3.4.2 Preanalytics on site
The blood gas analysis is evaluated on site using a blood gas analyzer (e.g. ABL 90).

The analysis is either performed immediately or the capillary is sealed with a cap and analyzed after completion of the spiroergometry.

The following parameters are recorded at rest, in the anaerobic threshold range and during maximum load:
- pH value
- peripheral oxygen saturation (SO₂)
- partial pressure of oxygen (pO₂)
- partial pressure of carbon dioxide (pCO₂)
- base excess (BE)
  - bicarbonate (HCO₃⁻)
  - lactate
3.4.3 After the measurement

a) printout the exercise ECG

b) activate the blood gas mode and enter data (optional)

c) printout the findings

3.4.4 Follow-up discussion, feedback on findings

Whether and which information is shared with the participant has to be defined in the respective study protocol.

3.4.5 Evaluation / reporting of the examination

The evaluation of the spiroergometry data follows the recommendation of the EACPR and AHA [1]. It should be performed offline using appropriate software (e.g. JLAB, CareFusion Corporation, San Diego, USA) following the steps below, manual evaluation is also possible:

1. Checking the settings
   - **Standard**: Averaging of the respiratory gas analyses over 30 seconds

2. Plausibility check
   - **Review the following plausibility criteria using the 9-field chart**:
     - RER implausible if e.g. below 0.7 at rest
     - VE implausible if the respiratory minute volume is too low (rule of nine: increase of about 9 I/25 watts)
     - **Aerobic capacity** implausible if the VO₂ increase/watt is too low (rule of thumb in healthy individuals: power (watts) x 10 ml)

3. Determining the VO₂ peak:
   - **Highest VO₂ value achieved during exercise**. A reliable statement about VO₂ peak is only possible if an RER >1.05 was achieved during exercise.

4. Determining the anaerobic threshold (AT or VT1):
   - AT/VT1 is determined in the range one minute after starting the exercise until RER = 1, either by determining the change in the slope of the VE/VCO₂ curve (field 5) or the increase in oxygen equivalent (EQO₂) in field 6.

5. Determining the respiratory compensation point (RCP or VT2):
   - The RCP is the point at which there is a disproportionate increase in VE to VCO₂, read as the increase in EQCO₂ in field 6.
3.5 DEALING WITH DEVIATIONS

Documentation/handling of/with irregularities

During the stress test, the participant may experience clinical complaints, ECG and blood pressure abnormalities or oxygen uptake disorders, which were mentioned in particular in the termination criteria. If any of these changes occur, the physician responsible for monitoring spiroergometry should be consulted in order to decide whether to continue or discontinue the examination. These abnormalities are documented in the software in the field for termination criteria.

Emergency equipment including a defibrillator and emergency kit must be available to provide first aid. If it is foreseeable that the incident requires extended medical care, inform the rescue coordination center by calling the emergency number 112 or a resuscitation team.

Termination criteria

Objective termination criteria include:
- ST-segment depressions (> 0.2 mV) or elevations
- progressive atrial or ventricular arrhythmia or block patterns
- new onset of atrial fibrillation
- rate decrease during exercise
- absence of RR rise or RR fall across 2 exercise levels
- decrease of O₂ uptake (or oxygen pulse) despite increase of load

Subjective termination criteria include:
- maximum exhaustion (e.g. of the legs)
- chest pain (e.g. AP symptoms), severe dizziness
- excessive dyspnea
- participant signals desire to terminate
4 DATA MANAGEMENT

Paper version/findings sheets

One complete report (including the ECG registration) is printed out in a paper version and archived chronologically.

Data flow

The data is stored locally in the PC. The data should be additionally secured by regular/daily backups.

Currently, all relevant information is entered manually into the eCRF. The following information should be obtained in all DZHK studies/registers:

1. process-related information:

   - date of the examination (dd.mm.yyyy)
   - cardiac pacemaker (yes/no/unknown/not assessed)
   - cardiac rhythm (sinus rhythm/atrial fibrillation/pacemaker rhythm)
   - use of beta-blockers (yes/no/unknown/not assessed)
   - duration of exercise (mm:ss)
   - type of exercise
     - treadmill with indication of specific protocol (drop-down list: Bruce protocol / modified Bruce protocol / modified Naughton protocol)
     - bicycle with indication of specific protocol (selection list: modified Jones protocol / WHO protocol)
   - Specify reason for termination
     - maximum exertion reached (Alternative criteria: RER > 1.1 [in exercise phase], heart rate > 80% of the age- / sex-specific /sex-specific set point (= 220/200-lifetime; caveat: beta-blockers), lactate > 4mM, VO2 plateau [usually only in very well-trained people = Vmax])
     - ST-segment depression (> 0.2 mV) or elevation
     - progressive atrial or ventricular arrhythmia or block patterns
     - new onset of atrial fibrillation
     - rate decrease during exercise
     - absence of RR rise or RR fall across 2 exercise levels
     - decrease of O2 uptake (or oxygen pulse) despite increase of load
     - maximum exhaustion (e.g. of the legs)
     - chest pain (e.g. AP symptoms), severe dizziness
     - excessive dyspnea
- participant signals desire to examiner to terminate

2. Findings

- Standard measurements (see "Standard parameters", Abbreviations and definitions, chapter 1)

5 LITERATURE AND REFERENCES


6 MODIFICATIONS

Modifications as compared to the previous version.

<table>
<thead>
<tr>
<th>Section</th>
<th>Description of the modifications as compared to the previous version</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.2.6</td>
<td>Editorial changes</td>
</tr>
<tr>
<td>3.3.4</td>
<td>Editorial changes</td>
</tr>
<tr>
<td>4</td>
<td>Definition of load limit</td>
</tr>
<tr>
<td>8.2</td>
<td>Supplementary information on treadmill logs</td>
</tr>
</tbody>
</table>

7 LIST OF CONTRIBUTORS

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
<th>Involvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prof. Dr. Marcus Dörr</td>
<td>First author</td>
<td>Drafted the SOP</td>
</tr>
<tr>
<td>S. Kaczmarek</td>
<td>Author</td>
<td>Co-drafted the SOP</td>
</tr>
<tr>
<td>PD Dr. Frank Edelmann</td>
<td>Reviewer</td>
<td>Expert review</td>
</tr>
<tr>
<td>Dr. Natalie Arnold</td>
<td>WG Data standardization</td>
<td>Scientific review</td>
</tr>
<tr>
<td>Prof. Marcus Dörr</td>
<td>WG Data standardization</td>
<td>Scientific review</td>
</tr>
<tr>
<td>Prof. Frank Edelmann</td>
<td>WG Data standardization</td>
<td>Scientific review</td>
</tr>
<tr>
<td>Dr. Christoph Gertler</td>
<td>WG Data standardization</td>
<td>Scientific review</td>
</tr>
<tr>
<td>Prof. Stefan Kääb</td>
<td>WG Data standardization</td>
<td>Scientific review</td>
</tr>
<tr>
<td>Prof. Till Keller</td>
<td>WG Data standardization</td>
<td>Scientific review</td>
</tr>
<tr>
<td>Dr. Monika Kraus</td>
<td>WG Data standardization</td>
<td>Scientific review</td>
</tr>
<tr>
<td>Dr. Kristin Lehner</td>
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<td>Scientific review</td>
</tr>
<tr>
<td>Prof. Benjamin Meder</td>
<td>WG Data standardization</td>
<td>Scientific review</td>
</tr>
<tr>
<td>Prof. Eike Nagel</td>
<td>WG Data standardization</td>
<td>Scientific review</td>
</tr>
<tr>
<td>Prof. Matthias Nauck</td>
<td>WG Data standardization</td>
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<tr>
<td>Dr. Jürgen Prochaska</td>
<td>WG Data standardization</td>
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<tr>
<td>PD Dr. Anja Sandek</td>
<td>WG Data standardization</td>
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<tr>
<td>Christian Schäfer</td>
<td>WG Data standardization</td>
<td>Scientific review</td>
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<tr>
<td>Dipl.-Ing. Jens Schaller</td>
<td>WG Data standardization</td>
<td>Scientific review</td>
</tr>
<tr>
<td>Tabea Scharfe</td>
<td>WG Data standardization</td>
<td>Scientific review</td>
</tr>
<tr>
<td>Prof. Renate Schnabel</td>
<td>WG Data standardization</td>
<td>Scientific review</td>
</tr>
<tr>
<td>Dr. Farbod Sedaghat-Hamedani</td>
<td>WG Data standardization</td>
<td>Scientific review</td>
</tr>
<tr>
<td>Dana Stahl</td>
<td>WG Data standardization</td>
<td>Scientific review</td>
</tr>
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The text elements highlighted in gray in this SOP are mandatory (= basic data set). The text elements that are not highlighted must be adhered to if possible.
8 APPENDIX

8.1 ECRF MODULE

<table>
<thead>
<tr>
<th>Spiroergometry</th>
<th>(21.06.2023 - 14:30:05 [CEST])</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Examination details</strong></td>
<td></td>
</tr>
<tr>
<td>I. Was the cardiopulmonary exercise testing performed?</td>
<td>□ yes □ no □ unknown □ not assessed</td>
</tr>
<tr>
<td>II. Date of examination</td>
<td>□ dd.mm.yyyy □ unknown □ not assessed</td>
</tr>
<tr>
<td>III. Quality level</td>
<td>□ 1</td>
</tr>
</tbody>
</table>

**Help:**
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).

<table>
<thead>
<tr>
<th>Examination</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Pacemaker*</td>
<td>□ yes □ no □ unknown □ not assessed</td>
</tr>
<tr>
<td>2. Cardiac rhythm*</td>
<td>□ sinus □ atrial □ pacemaker □ unknown □ not assessed</td>
</tr>
<tr>
<td>3. Use of beta blockers*</td>
<td>□ yes □ no □ unknown □ not assessed</td>
</tr>
<tr>
<td>4. Duration of exercise*</td>
<td>□ minutes □ unknown □ not assessed</td>
</tr>
<tr>
<td>5. Type of exercise*</td>
<td>Treadmill</td>
</tr>
<tr>
<td></td>
<td>Bicycle</td>
</tr>
<tr>
<td>6. Reason for termination*</td>
<td></td>
</tr>
</tbody>
</table>

**Help:**
maximum exercise reached:
(Alternative criteria: REF > 1.1 [in exercise phase], heart rate > 80% of the age-/sex-specific/ex-specific set point [e.g. 220/200-lifetime; caveat: beta-blockers], lactate > 4mM. VO2 plateau [usually only in very well-trained people = Vmax]).

<table>
<thead>
<tr>
<th>Examination details</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>7. HR (at rest)*</td>
<td>□ min □ unknown □ not assessed</td>
</tr>
<tr>
<td>8. Maximum HR (during exercise)*</td>
<td>□ min □ unknown □ not assessed</td>
</tr>
<tr>
<td>9. HR (1 minute after exercise)*</td>
<td>□ min □ unknown □ not assessed</td>
</tr>
<tr>
<td>10. RRays (at rest)*</td>
<td>□ mmHg □ unknown □ not assessed</td>
</tr>
<tr>
<td>11. RRDs (at rest)*</td>
<td>□ mmHg □ unknown □ not assessed</td>
</tr>
</tbody>
</table>

The text elements highlighted in gray in this SOP are mandatory (= basic data set). The text elements that are not highlighted must be adhered to if possible.
12. RRsys (during exercise)*
   - mmHg
   - unknown
   - not assessed

13. RRdta (during exercise)*
   - mmHg
   - unknown
   - not assessed

14. Watt (max)*
   - Watt
   - unknown
   - not assessed

15. VE/VCO2 (at rest)*
   - unknown
   - not assessed

16. VE/VCO2 (during exercise)*
   - unknown
   - not assessed

17. PET CO2 (at rest)*
   - mmHg
   - unknown
   - not assessed

18. PET CO2 (during exercise)*
   - mmHg
   - unknown
   - not assessed

19. VE/VCO2 slope*
   - unknown
   - not assessed

20. VO2 (at rest)*
   - ml/min
   - unknown
   - not assessed

21. VO2 peak*
   - ml/min
   - unknown
   - not assessed

22. VO2 Norm*
   - ml/min
   - unknown
   - not assessed

23. VO2 AT*
   - ml/min
   - unknown
   - not assessed

24. VE max*
   - l/min
   - unknown
   - not assessed

25. BF (respiratory rate) (at rest)*
   - l/min
   - unknown
   - not assessed

26. BF (during exercise)*
   - l/min
   - unknown
   - not assessed

27. Maximum BF*
   - l/min
   - unknown
   - not assessed

The text elements highlighted in gray in this SOP are mandatory (= basic data set). The text elements that are not highlighted must be adhered to if possible.
<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>29. VT (during exercise)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30. VT/VT (at rest)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>31. VT/VT (during exercise)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>32. Saturation sO2 (at rest)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>33. Saturation sO2 (during exercise)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>34. Respiratory quotient (RQ) at rest*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>35. Respiratory quotient (RQ) during exercise*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>36. Respiratory quotient after end of exercise (RQ maxpost)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>37. Used BORG scale*</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Borg rating of perceived exertion scale (6-20)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Borg – dyspnea scale</td>
<td></td>
</tr>
</tbody>
</table>

Possible entries

Please select one of the following entries for the corresponding items marked above.

1) 1
2) 2
3) 3

2) Bruce protocol
   - modified Bruce protocol
   - modified Naughton protocol
   - unknown
   - not assessed

3) modified Jones protocol
   - WHO protocol
   - unknown
   - not assessed

The text elements highlighted in gray in this SOP are mandatory (= basic data set). The text elements that are not highlighted must be adhered to if possible.
4) maximum exertion reached
   ST segment depression (> 0.2 mV) or elevation
   progressive atrial or ventricular arrhythmias or
   block patterns
   new onset of atrial fibrillation
   rate decrease during exercise
   absence of RR rise or RR fall across 2 exercise
   levels
   decrease of O2 uptake (or oxygen pulse) despite
   increase of load
   maximum exhaustion (e.g. of the legs)
   chest pain (e.g. AP symptoms), severe dizziness
   excessive dyspnea
   participant signals desire to examiner to terminate
   unknown
   not assessed

5) 0 - 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

6) 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 dyspnea
    unknown
    not assessed
8.2 CYCLE AND TREADMILL PROTOCOLS

The following exercise protocols are some of those used within the scope of DZHK studies and registers; this list can be continuously upgraded as needed:

1. Cycle ergometry

a) Modified Jones protocol [2]:

- 3-minute resting phase
- Start exercise with 20 Watts, then increase by 16 Watts every minute; symptom-limited termination of the exercise
- Advantage: availability of German reference values from a large sample of a population-based study [3-5].

b) WHO protocol [6, 7]:

- 3-minute resting phase
- Start exercise with 25 Watts, then increase by 25 Watts every 2 minutes; symptom-limited termination of the exercise.

2. Treadmill cardiopulmonary exercise test

a) Bruce protocol [8]:

- 3-minute resting phase
- Symptom-limited exercise in 6 stages (3 minutes per stage) with varying speeds and slopes:

<table>
<thead>
<tr>
<th>Stage</th>
<th>Speed (km/h)</th>
<th>Slope (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2.7</td>
<td>10</td>
</tr>
<tr>
<td>2</td>
<td>2.7</td>
<td>12</td>
</tr>
<tr>
<td>3</td>
<td>2.7</td>
<td>14</td>
</tr>
<tr>
<td>4</td>
<td>4.0</td>
<td>16</td>
</tr>
<tr>
<td>5</td>
<td>5.4</td>
<td>18</td>
</tr>
<tr>
<td>6</td>
<td>6.7</td>
<td>20</td>
</tr>
</tbody>
</table>

b) modified Bruce protocol [9]

- 3-minute resting phase
- Symptom-limited exercise in 9 stages (3 minutes per stage) with varying speeds and slopes:
Stage | Speed (km/h) | Slope (%)  
---|-------------|------------
1  | 2.7         | 0          
2  | 2.7         | 5          
3  | 2.7         | 10         
4  | 4.0         | 12         
5  | 5.4         | 14         
6  | 6.7         | 16         
7  | 8.0         | 18         
8  | 8.8         | 20         

**c) modified Naughton protocol [8]**

- 3-minute resting phase
- Symptom-limited exercise in 13 stages (2 minutes per stage) with varying speeds and slopes

| Stage | Speed (km/h) | Slope (%)  
---|-------------|------------
1  | 1.6         | 0          
2  | 2.4         | 0          
3  | 3.2         | 3.5        
4  | 3.2         | 7          
5  | 3.2         | 10.5       
6  | 4.8         | 7.5        
7  | 4.8         | 10         
8  | 4.8         | 12.5       
9  | 4.8         | 15         
10 | 4.8         | 17.5       
11 | 4.8         | 20         
12 | 4.8         | 22.5       
13 | 4.8         | 25         

The text elements highlighted in gray in this SOP are mandatory (= basic data set). The text elements that are not highlighted must be adhered to if possible.
8.3 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 [8, 9]. 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) [8, 9].

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.

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 Ratings of Perceived Exercise**

Subjectively perceived exertion with exercise according to Borg [10, 11]:

<table>
<thead>
<tr>
<th>6</th>
<th>No exertion at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>Extremely light</td>
</tr>
<tr>
<td>8</td>
<td>Very light</td>
</tr>
<tr>
<td>9</td>
<td>Light</td>
</tr>
<tr>
<td>10</td>
<td>Somewhat hard</td>
</tr>
<tr>
<td>11</td>
<td>Hard (heavy)</td>
</tr>
<tr>
<td>12</td>
<td>Very hard</td>
</tr>
<tr>
<td>13</td>
<td>Extremely hard</td>
</tr>
<tr>
<td>14</td>
<td>Maximal exertion</td>
</tr>
</tbody>
</table>

**BORG Dyspnoea Scale**

Subjectively perceived dyspnoea according to Borg [12]:

<table>
<thead>
<tr>
<th>0</th>
<th>Nothing at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5</td>
<td>Very, very slight (just noticeable)</td>
</tr>
<tr>
<td>1</td>
<td>Very slight</td>
</tr>
<tr>
<td>2</td>
<td>Slight</td>
</tr>
<tr>
<td>3</td>
<td>Moderate</td>
</tr>
<tr>
<td>4</td>
<td>Somewhat severe</td>
</tr>
<tr>
<td>5</td>
<td>Severe</td>
</tr>
<tr>
<td>6</td>
<td>Severe to very severe</td>
</tr>
<tr>
<td>7</td>
<td>Very severe</td>
</tr>
<tr>
<td>8</td>
<td>Very severe to very, very severe</td>
</tr>
<tr>
<td>9</td>
<td>Very, very severe (almost maximal)</td>
</tr>
<tr>
<td>10</td>
<td>Maximal dyspnoea</td>
</tr>
</tbody>
</table>