## XPRIZE HEALTHSPAN | CLINICAL PROTOCOL

# Cardiopulmonary Exercise Testing

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**PROTOCOL**

# Cardiopulmonary Exercise Testing

## 1 GENERAL DESCRIPTION

Cardiopulmonary exercise testing (CPET) is the gold standard performance-based measure of endurance capacity and aerobic fitness [1, 2]. It is a maximal, relatively non-invasive test that assesses the integrative physiological responses involving the pulmonary, cardiovascular, hematopoietic, neuropsychological, and skeletal muscle systems through exercise stimulation. CPET is performed using a treadmill or cycle ergometer with simultaneous measurement of respiratory gas exchange, including oxygen uptake, carbon dioxide production, and ventilatory parameters.

For the XPRIZE Healthspan Competition, CPET will follow the standardized incremental protocols in accordance with the European Respiratory Society (ERS) guidelines [2].

The **primary measure for judging** is peak $V'O_2$, defined as the highest 30-second average of oxygen uptake (L/min) achieved during the exercise test prior to the recovery phase.

**The following protocol is a <u>minimum recommended standard</u> that all competing teams are expected to follow. Any deviations from this protocol must be documented and submitted to XPRIZE-Utah DCC with a justification.**

*Note: The following protocol is based on the European Respiratory Society (ERS) guidelines [2] and incorporates elements of the Study of Muscle, Mobility, and Aging (SOMMA) CPET protocol [3]. For the XPRIZE Healthspan Competition, treadmill-based CPET is recommended when feasible. Competing teams may adopt alternative protocols already in use at their clinical sites but must adhere to the minimum recommended standards described below.*

## 2 SAFETY ISSUES

<u>Absolute contraindications for CPET:</u>

- Uncontrolled cardiovascular conditions, including: acute myocardial infarction, left main coronary stenosis or its equivalent, unstable angina, moderate or severe stenotic valvular heart disease, symptomatic uncontrolled arrhythmias including atrial fibrillation with uncontrolled ventricular rate, severe untreated arterial hypertension, syncope, tachyarrhythmias/bradyarrhythmias, active endocarditis, high-degree atrioventricular block, acute myocarditis or

pericarditis, hypertrophic cardiomyopathy, uncontrolled heart failure, suspected dissecting aneurysm, deep venous thrombosis of lower limbs.
- Uncontrolled respiratory conditions, including: pulmonary embolism, pulmonary edema, severe pulmonary arterial hypertension, uncontrolled asthma.
- Uncontrolled non-cardiorespiratory conditions affecting or aggravated by exercise, such as infection, renal failure, thyrotoxicosis, acute bleeding, electrolyte abnormalities.
- Required supplemental oxygen during testing

Special considerations: Participants with diabetes mellitus should have blood glucose measured prior to testing to reduce the risk of hypoglycemia. CPET should not be performed in participants with blood glucose ≤ 2.8mmol/L or 50mg/dL or with a hyperglycemic event in the previous 24 hours requiring assistance.

Relative contraindications for CPET:

- Orthopedic impairment that compromises exercise performance
- Mental or cognitive impairment leading to an inability to cooperate

Absolute reasons for immediately stopping a CPET:

- Decrease in systolic blood pressure >20mmHg compared to the highest recording during the test despite increasing workload, especially if accompanied by signs or symptoms
- Suspected myocardial infarction
- Moderate to severe chest pain
- Moderate or unusual shortness of breath
- Increasing dizziness, near-syncope, or syncope
- Heart block with slowing of ventricular rhythm
- ECG ST-segment depressions (horizontal to downsloping >2mm)
- Signs of poor perfusion (circulation or blood flow), including pallor (pale appearance to the skin), cyanosis (bluish discoloration), or cold and clammy skin
- Central nervous system symptoms
- Technical inability to adequately monitor the ECG
- Participant request to stop

Relative reasons for stopping a CPET include:

- Severe hypertension, defined as systolic blood pressure ≥250mmHg and diastolic blood pressure ≥120mmHg
- Progressive chest pain
- Physical or verbal manifestations of shortness of breath or severe fatigue
- Wheezing
- Leg cramps or intermittent claudication (Grade 3 on a 4-point scale)
- Pronounced ECG changes from baseline

Examiners should be trained to recognize abnormal physiological responses, identify indications for test termination, and respond appropriately. If a test is stopped for any of these reasons, the participant should sit or lie supine, as appropriate, depending on the severity of the event and the examiner's assessment of the severity of the event and the risk of syncope. Continuous monitoring, including ECG, blood pressure, $SpO_2$, and symptoms, should continue until stable.

# 3 GENERAL TRAINING GUIDELINES

Examiners should have prior clinical experience with exercise stress testing. Generally, examiners should have knowledge of the following:

- Appropriate indications of exercise testing
- Appropriate contraindications, risks, and risk assessment of testing
- Principles and details of stress testing, including proper ECG lead placement and skin preparation
- Prompt recognition of complications of exercise testing
- Various exercise protocols and indications of each
- Basic cardiovascular and exercise physiology, including hemodynamic responses to exercise
- Prompt recognition of cardiac arrhythmias
- Cardiovascular drugs and how they may affect test performance
- How age and disease may affect test performance
- Testing end points and indications to terminate exercise testing
- Electrocardiography, including ECG changes that may result from exercise, hyperventilation, ischemia, hypertrophy, and conduction disorders.

Examiners must be trained to a consistent level of proficiency in administering CPET using the designated testing equipment. At a minimum, training should include:

- Reviewing the manufacturer's user guide and operating manual to understand: 1) proper equipment setup and operation, 2) safety considerations and exclusion criteria, and 3) detailed testing procedures.
- Practicing administering the test at the trial site using other study members or volunteers who are unfamiliar with the testing procedures until reliable measurements are achieved.

Examiners who are unfamiliar with the designated testing equipment should also be given the opportunity to observe testing performed by an experienced examiner and to discuss any questions or potential issues with qualified study personnel. Upon training completion, examiners should be able to demonstrate proper equipment setup and conduct the assessments on two volunteers according to the protocol under the supervision of an experienced examiner. Examiners should have Basic Life Support credential and any required medical license as appropriate. For most participants, exercise testing can be

safely supervised by properly trained nurses, physician assistants, exercise physiologists, physical therapists, or medical technicians working under the direct supervision of a physician (or physician delegate) to complete initial assessments and to response in case of any instability. It is recommended that examiners perform CPET at least once a month to maintain requisite familiarity.

*Note: To minimize variability across visits, the following procedures should be kept consistent for each participant whenever possible: testing equipment, testing environment, time of day, examiner, participant assessment and preparation procedures, use of supplemental oxygen and medications, indications for test cessation, quality assurance procedures, and order of testing procedures. Any deviations from these procedures should be documented, including the reason for the deviation.*

# 4 TESTING ENVIRONMENT

The testing environment should be quiet and private. To minimize participant anxiety, examiners should maintain a calm, relaxed, and confident demeanor and provide clear explanations of the testing procedures. To maintain participant comfort, room temperature and ventilation should be controlled as much as possible. It is recommended to keep the temperature to be 20-22°C, as cold air may foster bronchospasm in susceptible individuals.

# 5 REQUIRED EQUIPMENT AND SUPPLIES

1. Monitoring Equipment:
    a. 12-lead electrocardiograph (ECG) system with real-time display
    b. Blood pressure monitoring equipment: automated monitor or manual cuff with stethoscope
    c. Pulse oximeter
2. Ergometer: cycle ergometer or motor-driven treadmill
3. Metabolic Measurement System:
    a. Metabolic cart capable of breath-by-breath analysis, including: gas analyzer ($O_2$ and $CO_2$), volume/flow sensor (e.g., pneumotach), airflow transducers, and real-time breath-by-breath data display.
4. Respiratory Interface:
    a. Facemask or mouthpiece
    b. Nose clip
5. Pulmonary Function Equipment:
    a. Spirometer
    b. Calibration syringe
6. Other Supplies:
    a. ECG electrodes
    b. Razor

   c. Alcohol swabs
   d. Gauze
   e. Code cart
7. Documentation: Participant's medical history and medication inventory

# 6 EQUIPMENT REQUIREMENTS/SETUP

All testing equipment should be set up and maintained according to the manufacturer's user guide and operating manual and calibrated according to the manufacturer's recommendations, or more frequently depending on usage. All equipment calibrations should be properly documented. Examiners should inspect the equipment for any mechanical or software issues prior to use.

**Cycle ergometer:** The cycle ergometer must meet the following requirements:

1. Capable of adjusting work rate in increments steps, either automatically (electronically braked cycling) or manually (mechanically braked cycling)
2. Equipped with:
   a. Adjustable handlebars and seat to ensure proper positioning, with the knee slightly flexed at the lowest pedal position
   b. Clear and appropriately sized meters, dials, or digital displays for easy reading.

Adaptable pedal grips (i.e., to fix the patients' shoes on the pedal) are recommended to optimize performance and increase patient safety. Regular calibration of the equipment, including measurements of crank arm torque at various speeds using a certified instrument, is necessary following the manufacturer's specifications. Verification of calibration should be done annually and after each service/repair of the ergometer.

**Motor-driven Treadmill:** The treadmill must meet the following requirements:

1. Minimum dimension of approximately 127cm in length and 41cm in width
2. Accommodate body weights up to 150 kg.
3. Equipped with:
   a. A padded front rail and at least one side rail should be present to optimize patient safety
   b. An emergency stop button that is clearly visible and easily accessible

Regular calibration of the equipment is necessary following the manufacturer's specifications. Verification of calibration should be done annually and after each service/repair of the treadmill. Verification of speed and inclination readings of the treadmill should be done annually.

Special considerations: For patients with lung diseases, it is essential that the treadmill offers very slow walking speed (e.g., 1km/h) and allows inclination of choice.

**Respiratory Interface:**

Participants can be interfaced to the metabolic cart system using either a bite-block mouthpiece or a facemask assembly. The selected interface should ensure minimal air leakage, participant comfort, and accurate gas exchange measurements.

**Pulse oximetry:**

Pulse oximetry is used to monitor oxygen saturation ($SpO_2$) during CPET. Sensor placement (i.e., finger, earlobe, nose, forehead) should be optimized to ensure the stability and reliability of SpO2 recordings.

**Electrocardiograph (ECG):**

The ECG system must meet the specifications set by the American Heart Association (AHA) [4]. Continuous ECG monitoring should be maintained throughout the test.

**Blood Pressure Monitoring:**

Blood pressure may be measured using either an automated device or manual auscultation. For manual measurement:

- Appropriately sized cuffs must be available
- The cuff should be positioned at the level of the heart
- The apparatus should be calibrated

Blood pressure should be measured at regular intervals, **preferably every two minutes**, during CPET.

**Metabolic carts:**

The metabolic cart must comply with the American Thoracic Society (ATS)/European Respiratory Society (ERS) standards for flow and gas exchange measurements [5]. Specifically, it must include:

- Capability for breath-by-breath analysis
- Gas analyzer, including:
    - Oxygen ($O_2$) using paramagnetic or electrochemical cell technology
    - Carbon dioxide ($CO_2$) using non-dispersive infrared sensor technology or thermal conductivity
    - Mass spectrometry systems are also acceptable
- Low dead space and low resistance to breathing flows
- Immune to temperature changes, humidity, and saliva accumulation

Minimum requirements of gas analyzers sensors' performance for measurements during room-air breathing are:

- For $O_2$: a detection range between 0-100%
- For $CO_2$: a detection range between 0-10%
- Accuracy of ±1%
- Rapid response time (e.g., <13ms)

- Two-point calibration for each sensor is required: one in the range of ambient concentration and the other in the range of exhaled concentration. Preferably, use two calibration gases with known concentrations rather than only one gas and room air.

A global functioning check should be performed regularly to ensure correct ventilatory and gas exchange calculation. The pick-up lead for sampling inspiratory and expiratory gas should be replaced regularly, preferably every 3-6 months, and changed between participants to avoid cross infection.

**Validity Check:**

A validity check is required to detect and correct equipment malfunctions before and during CPET (e.g., mask leakage, defect or drift of the gas analyzers). A simplified validity check based on the following considerations is recommended:

- Adequate minute ventilation (V'E): Implausible if the increase of V'E does not follow an increase in work rate.
- Adequate oxygen uptake ($V'O_2$): Implausible if the increase of $V'O_2$ is too low during the first 1-2 minutes of CPET.
- Adequate respiratory exchange ratio (RER): Implausible if RER at rest is <0.7 or RER during the first 1-2 minutes of CPET is >1.

# 7 PARTICIPANT PREPARATION

The guidelines in this section are for participant comfort and optimal performance. Should a participant not follow these instructions, the testing is still permitted.

1. Participants should wear comfortable clothing and appropriate shoes suitable for exercise.
2. Participants should avoid strenuous exercise for at least 24 hours before testing, avoid caffeine on the day of the test, avoid smoking for at least 8 hours prior to the test, and avoid alcohol for at least 12 hours prior to the test.
3. Eating and drinking before CPET should be coordinated with the overall visit schedule, including any fasting requirements for biospecimen collection. When feasible, participants should refrain from eating for at least 2 hours before testing.
4. Participants should take their usual medications. The type of medication, dose, and number of hours since the medication was taken before the test should be recorded.

Special considerations: Participants currently taking bronchodilators should administer their usual bronchodilator treatment at least 10 minutes prior to testing, unless otherwise directed by a physician or the study protocol.

# 8 PRIOR TO THE TEST

1. Ensure that the participant is wearing appropriate clothing and footwear.
2. Confirm that all required documentation is available in the participant's file prior to the test administration. This may include: consent and screening forms, data recording sheets, and any related testing documents.
3. Measure the participant's height and weight, if not already collected during the visit.
4. Measure the participant's vital signs, including heart rate, blood pressure, $SpO_2$, and body temperature.
5. Review the participant's medical history and current medications.
6. Check for contraindications. Do not perform the test if the participant has any of the absolute contraindications specified in the Safety Issues section. Notify the supervising physician (or physician delegate) if any significant abnormalities are identified.

- *Special considerations: For participants with diabetes mellitus, blood glucose should be measured before exercise. Do not perform the test if participants have severe hypoglycemia, defined as a blood glucose ≤2.8mmol/L or 50mg/dL, or a hyperglycemic event in the previous 24h requiring assistance.*
- *Note: The supervising physician (or physician delegate) should determine whether the participant is safe to perform the CPET based on medical history, current medications, and clinical status. Depending on the judgment of the supervising physician (or physician delegate), the CPET may be canceled (or postponed), or only the submaximal CPET (resting, unloaded, and recovery phase) will be completed.*

7. Ask the participant how they are feeling. Notify the supervising physician (or physician delegate) if the participant reports significant symptoms such as pain, dyspnea, dizziness, vision changes, focal weakness, or other signs of instability.
8. Provide a general description of CPET and the associated testing protocol using a **standardized script**.
9. Inform the participant that sensations such as shortness of breath and a heightened sensation of leg effort are to be expected during the test, and that their perception of these symptoms is important for test interpretation. Emphasize that the test may be terminated at any time at the participant's request. Encourage the participant to exercise to near maximal capacity, as this will improve the quality and interpretability of the data.

- *Note: For treadmill testing, participants should be discouraged from using handrail support, as this may alter the metabolic cost of locomotion.*

10. Introduce the Borg Rating of Perceived Exertion (RPE) scale (See Appendix A) and anchor it to the extremes of both "shortness of breath" and "leg effort". Read the following instructions to the participant: "*During every stage of*

*exercise, we are going to ask you about the intensity of your breathlessness and leg discomfort at that point in time. As you should avoid speaking during the test, you will use a finger of your hand to point which number between 6 and 20 best reflects the intensity of each of these sensations. A rating of "6" represents no exertion at all, and "20" indicates that you feel like it's the hardest and most difficult work you could possibly do, and when you are giving it your greatest effort. A rating of "13" indicates that the activity is a challenge for you, you are sweating a little and you are breathing harder and faster, but you can still talk and continue. A rating of "17" indicates that the activity is strenuous for you, you are sweating a lot, your legs are tired, and you are breathing so heavily that it's hard to talk. Do you have questions about the scale?"* The examiner should repeat the selected number out loud to confirm the participant's selected number.

11. If required by the competing team's CPET protocol or if ventilatory reserve will be calculated, perform spirometry to obtain forced expiratory volume in one second ($FEV_1$) and, if available, a direct measurement of maximum voluntary ventilation (MVV). If spirometry or MVV is not performed, this should be documented.
12. Perform calibration of the flow sensor and the gas analyzers of the metabolic cart.
13. Attach the mask (or mouthpiece) to the participant.
14. Connect monitoring equipment to the participant (e.g., ECG leads, pulse oximeter, blood pressure cuff).

<u>Equipment familiarization:</u>

1. Participants without prior experience using an ergometer may experience poor coordination and/or anxiety that could affect test performance. For these participants, an optional familiarization step should be included.
2. The familiarization step should occur after the participant has been cleared for testing by the supervising physician (or physician delegate). The examiner should explain the process of walking on a treadmill or using a cycle ergometer, as applicable.
3. Ask the participant to step onto the treadmill or cycle ergometer. The device should begin at rest or the slowest possible speed and gradually increase to a comfortable pace, as tolerated. During this time, the examiner should emphasize proper positioning, regular breathing, and maintaining a forward gaze.
4. The duration for the familiarization step may vary but should not exceed five minutes total.
5. At least 10 minutes should elapse between the end of the familiarization step and the beginning of the resting phase.

# 9 DURING THE TEST

Briefly remind the participant about the CPET testing protocol using a **standardized script**. During all phases of testing, the examiner should provide clear, calm, and standardized instructions. Consistent verbal encouragement should be provided throughout the test to ensure participant understanding, maximize effort and standardize test conditions and minimize variability in test performance across participants and study visits.

**Resting phase:**

1. The resting phase should last up to three minutes, or as long as required to ensure that the system is working properly and to obtain accurate and stable baseline measurements prior to the initiation of exercise. Allow the participant to adapt to the testing apparatus (e.g, facemask or mouthpiece, ergometer, ECG leads).
2. Perform baseline measurements of $SpO_2$, ECG, blood pressure, minute ventilation (V'E) and gas exchange variables, including the respiratory exchange ratio (RER). Measurements may be obtained during the final minute of the resting phase or once stable baseline values are achieved.
3. Transition immediately to the unloaded phase without interruption once stable baseline measurements are achieved.

**Unloaded phase:**

1. The unloaded phase should last up to 3 minutes and no shorter than 2 minutes.
    a. For cycle ergometer: the minimum work rate on the cycle ergometer should not exceed 10W.
    b. For treadmill: the lowest safe and feasible walking speed should be used for baseline measurements.
2. This phase serves as a transition from rest to exercise, allowing continued physiological adjustment and providing a low-intensity warm-up prior to the incremental exercise phase. It also allows assessment of baseline V'O2 and ventilation associated with vertical leg movements.
3. Assess perceived exertion, dyspnea, and leg fatigue using Borg RPE scale.
4. Transition immediately to the incremental exercise phase without interruption upon completion of the unloaded phase.

**Incremental exercise phase:**

1. The incremental exercise phase should last approximately 10 minutes (8-12 minutes) and be no shorter than 6 minutes.
2. This phase should consist of a continuous or stepwise increase in workload designed to achieve symptom-limited maximal effort.
3. Provide regular, standardized encouragement to encourage the participant to continue exercising and to reach near-maximal effort.

4. Remind the participant periodically to maintain consistent movement, avoid unnecessary upper body movement, breathe normally, and avoid talking during the test.
5. Competing teams should select incremental exercise protocols adapted to the participant's characteristics. However, the same incremental exercise protocol must be used on repeated visits for the same participant.
    a. For cycle ergometry: Competing teams may use either a continuously incrementing ramp protocol (e.g., increase of work rate every 2-15 seconds) or a minute-by-minute incremental protocol (e.g., increase of work rate in 5-30W/min) to symptom limited maximum, while maintaining a cadence of approximately 55-70 revolutions per minute (rpm).
    b. For treadmill testing: Competing teams are recommended to use a modified Balke protocol, which involves walking at a constant speed (e.g., approximately 5km/h) with progressive increases in workload through staged increments (e.g., 2-minute stages). Workload may be increased by increasing treadmill speed (e.g., by approximately 0.8km/hour) and/or incline (e.g., by 2.5%) to progressively increase workload. In general, the testing strategy is to initially increase treadmill speed to the highest levels of well-tolerated walking pace, followed by progressive increases in incline to further increase workload and exertion. For safety, treadmill incline should generally not exceed 10%. If sufficient exertion is not achieved at this workload, further increases in speed (e.g., 0.8km/h per stage) may be implemented as appropriate.
    c. Maximum effort: Criteria used to support determination of peak (i.e., symptom-limited maximal) effort may include:
        i. A plateau in $V'O_2$ despite increasing workload
        ii. Peak exercise ventilation (V'E) exceeds 85% of directly measured or estimated MVV, if MVV is available
        iii. Peak RER during exercise exceeding 1.05, accompanied by a Borg RPE scale score ≥17
        iv. Heart rate at or above the predicted values of maximum heart rate
        v. Peak $V'O_2$ exceeds $V'O_2$ at anaerobic threshold (AT) and comes close to the maximal predicted values of peak $V'O_2$, if AT and predicted peak $V'O_2$ are calculated. Peak $V'O_2$ is defined as the highest 30-second average of $V'O_2$ (L/min) achieved during the exercise test before recovery phase.
        vi. Peak work rate exceeds peak work rate predicted, if work rate is available
    - *Note: Importantly, CPET should not be stopped when these criteria are met.*

6. Assess perceived exertion, dyspnea, and leg fatigue using Borg RPE scale at regular intervals.
7. Transition immediately to the recovery phase without interruption upon completion of the incremental exercise phase or upon test termination.

**Recovery phase:**

1. The recovery period should last at least 2-3 minutes and is important for participant safety and monitoring recovery from exercise. A prolonged recovery period may be indicated based on the participant's clinical condition.
    a. For cycle ergometer: unloaded pedaling at a reduced cadence of approximately 30rpm.
    b. For treadmill: reduce treadmill speed to approximately 1.6km/h and lower treadmill incline to 0%.
2. Continue cardiovascular monitoring, including ECG, blood pressure, and $SpO_2$.
3. Measure heart rate.
4. Assess perceived exertion, dyspnea, and leg fatigue using Borg RPE scale.
5. Gas exchange measurements may be discontinued and the facemask/mouthpiece removed to improve participant comfort.

**Test termination:**

- Participants have the right to stop the test at any time for any reason. If a participant indicates that they would like to stop the test or appears unable to safely continue, the examiner should follow the following procedure:
    - Immediately stop the test.
    - Transition the participant to the recovery phase (e.g., unloaded pedaling or slow walking) if it is safe to continue low-intensity movement. If low-intensity movement is not safe or tolerated, assist the participant into a seated or supine position, as clinically indicated.
    - Continue close monitoring of ECG, blood pressure, and $SpO_2$.
    - Notify the supervising physician (or physician delegate) if any abnormal signs or symptoms are present.

# 10 AFTER THE TEST

1. Assist the participant in safely existing the testing machine
2. Allow the participant to sit and rest as needed
3. Congratulate the participant on good effort and offer a drink of water if available.
4. Complete the source document and ensure that all data are recorded accurately.

# REFERENCES

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# APPENDICES

## 10.1. Appendix A. Borg Rating of Perceived Exertion (RPE) Scale

| Borg RPE Scale Score | Interpretation |
|---|---|
| 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 |

*Note: XPRIZE Healthspan uses the original Borg Rating of Perceived Exertion (RPE) 6-20 Scale [6].*