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|----------------------|-------------------------------|---------------------|-------------------------------|
| ORGANIZATION: | [insert name of lab or study] | | |
| SOP TITLE: | 6-minute walk test | | |
| SOP Creation: | [insert date] | SOP VERSION: | [insert version control info] |

Sample: 6-Minute Walk Test

General Information

I. Purpose: *Briefly explain what the reader will know how to do after reading the document*

- a. This document is designed to assist study team members in proper and consistent administration of the 6-minute walk test (SMW). These parameters are not inflexible rules; rather they are guidelines intended to minimize between-tester variability and optimize subject safety. In particular, the study team may change these procedures based on the clinical status of the subject, space limitations or other noteworthy mitigating circumstances.

II. Scope: *Indicate the studies and/or staff members to which this document applies; be specific*

- a. This document applies to all studies that use the 6-minute walk (6MW) and all staff responsible for administration of the test and data entry.

III. Test Information: *Describe the test and any components and/or associated software or apps required; provide references if applicable*

The 6MW is a clinical assessment of an individual's functional capacity. This particular test is easy to administer, well-tolerated by subjects, and tends to reflect ability to participate in activities of daily living.

- a. The 2002 American Thoracic Society (ATS) Guidelines provide the foundation for our testing procedures
- b. American Journal of Respiratory and Critical Care Medicine, Vol. 166, No. 1(2002), pp. 111-117. doi: [10.1164/ajrccm.166.1.at1102](https://doi.org/10.1164/ajrccm.166.1.at1102)

IV. Indications for use: *Describe the purpose of the device within the context of your particular lab or project*

- a. A field test to evaluate functional capability in the absence of a need or capacity for stress testing

V. Contraindications to testing: *List conditions or states in which the test should not be administered*

Do not perform the test if any of the following are evident:

- a. Resting heart rate > 120 bpm
- b. Resting systolic blood pressure > 180 mmHg

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- c. Resting diastolic blood pressure > 100 mmHg
- d. Subject refuses to participate

VI. Absolute Indications for Test Termination

Stop the test immediately if any of the following are evident:

- a. Chest pain
- b. Intolerable dyspnea, shortness of breath or wheezing
- c. Leg cramps or claudication
- d. Diaphoresis (excessive sweating) or cold and clammy skin
- e. Pale or ashen skin appearance; lips losing color
- f. Light-headedness
- g. Staggering or unstable gait
- h. Subject requests to stop
- i. Physical or verbal manifestations of severe fatigue

VII. Relative Indications for Test Termination*

Use clinical judgment to determine whether to continue with test. A combination of criteria might warrant early termination; however when observed in isolation, none of the following require stopping the test early.

- a. Shortness of breath consistent with increase in physical activity
- b. Mild muscle pain or weakness
- c. Minor gait changes
- d. Subject-reported mild-moderate fatigue

**You may deviate from the required prompts if you deem it clinically necessary to ask about signs and symptoms exhibited by the subject.*

VIII. Qualifications of testing personnel: Describe what skills and/or experiences are necessary for staff responsible for this device; indicate if any certifications are required

- a. Familiarity with the current ATS Guidelines
- b. Minimum of 2 practice administrations
- c. OPTIONAL: Study-specific requirements
- d. Preferred: Current BLS certification

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IX. Equipment: *List all required equipment, space, and software; e.g. device, batteries, etc.*

- a. 30-50 meter length hallway, with start and finish marked
- b. Cones, one for each end of the course
- c. Timer
- d. Chair, for pre-test measurements & subject rest periods
- e. Automated blood pressure cuff (if possible)
- f. SpO₂ monitor
- g. Hard copy of Modified Borg Scale
- h. Measuring wheel

X. Definitions: *Define terms and phrases specific to the test*

XI. Staff responsibilities: *List tasks*

- a. Safety of the subject
- b. Follow the test protocol and/or record any deviations
- c. Allow the subject to walk at his/her own pace
 - i. Do not walk along with the subject
 - ii. Minimize talking with subject; restrict to specified language and prompts as indicated in this document*
 - iii. Before the start of the test, encourage the subject to walk briskly and to cover as much ground as possible
- d. Complete all fields on the case report form

Overview of Procedures: *This section is a chronological overview of what steps are necessary for distribution, data acquisition, compliance checks, data storage, etc.*

Include screen shots and images when appropriate.

Performing the SMW: *List step-by-step instructions for each element or step of the test: e.g. participant preparations, equipment calibration, etc. Be specific: outline any study or lab specific naming conventions for files and/or account names. Be sure to include any instructions regarding privacy and confidentiality.*

- a. Confirm course length (one length = 1 direction)
- b. Place a cone at each end
- c. Record pre-test heart rate, blood pressure and SpO₂ after a seated 10-minute rest
- d. Record pre-test shortness of breath using the Modified Borg Scale

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- i. SEE APPENDIX I FOR MODIFIED BORG SCALE
- e. Instruct subject to walk to starting cone
- f. Read the test instructions to the subject
 - i. SEE APPENDIX II FOR PRE-TEST LANGUAGE
- g. Demonstrate how to walk around a cone (subjects have a tendency to turn around before the cone)
- h. Instruct the subject to start walking when you say “Go”
- i. Start the timer as soon the subject starts walking
 - i. Tick off the lengths as the subject completes them (see case report form)
- j. Update the subject with time remaining every minute and with 15 seconds remaining in the test
 - i. SEE APPENDIX III FOR TIME POINT LANGUAGE
- k. At 6:00, say: “Stop”
 - i. Mark the spot where the subject stopped
- l. Record post-test shortness of breath using the Modified Borg Scale
- m. With subject seated, record post-test heart rate, blood pressure, SpO₂
- n. Use the measuring wheel to measure the distance covered by the subject in his/her last partial length
 - i. Record this number on the case report form
- o. If the post-test blood pressure is > 160mmHg SBP or >100mmHg DBP, re-take blood pressure after 10-minute recovery and inform provider
- p. Complete case report form: record any notes about:
 - i. Time and duration of subject breaks
 - ii. Symptoms reported by subject
 - iii. Occurrence(s) that might affect the outcome of the test
 - 1. Hallway traffic
 - 2. Equipment failure
 - 3. Tester error (e.g. stopping timer before 6 minutes has elapsed or not starting timer at the appropriate time)
 - 4. When in doubt, write it down

II. Subject-initiated breaks

- a. The subject may take breaks as often and for as long as they need to during the 6 minutes
- b. Do not stop the timers during the breaks
 - i. Record the time and duration of break on the case report form (Notes section)
- c. Ideally, the subject should remain standing during these breaks
 - i. For support, they may lean against the wall
 - ii. Bring the chair to subjects who look like they need seated rest or to those or request it

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Appendices: Use appendices to provide additional information

I. Borg Modified Scale

| | |
|-----|-------------------------------------|
| 0 | Nothing at all |
| 0.5 | Very, very slight (just noticeable) |
| 1 | Very slight |
| 2 | Slight (light) |
| 3 | Moderate |
| 4 | Somewhat severe |
| 5 | Severe (heavy) |
| 6 | |
| 7 | Very severe |
| 8 | |
| 9 | |
| 10 | Very, very severe (maximal) |

Scripts for dyspnea (shortness of breath) and fatigue

Please **grade** your **level of shortness of breath** using this scale.

If the subject has a hard time understanding what sensations, tell them to think about the following sensations:

- Feeling like **not getting enough oxygen** or air
- Feeling like **can't breathe deeply enough**
- Feeling of **tight chest**
- Feeling of having to **work harder than usual** to breathe

Please **grade** your level of **fatigue** using this scale.

For this study, fatigue refers to:

- Feeling of **tiredness**
- Feeling of **not having enough energy**
- Feeling of **need for rest**

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I. Pre-Test Language

- Today's test is a **standard test** used to **determine physical function** status in people with heart and lung problems.
- The **goal** of the test is to **walk as far as you can** in 6 minutes.
- You will **walk back and forth around these cones** (INDICATE CONES; DEMONSTRATE HOW TO WALK AROUND THE CONE) at a **speed** that will allow you to **make as many laps as possible** during the test.
- You will be **exerting yourself**; you might get **out of breath** or feel **tired**.
- You may **rest whenever you need to**, but **resume walking** as soon as you're able.
- If you **experience any symptoms**, please let us know.
- Remember, the goal is to **walk as far as possible** in 6 minutes.
- When I tell that you the **6-minutes are over**, **stop** where you are, and I will bring a chair to you.

II. Timepoint Language

- 1-minute: You are doing well. You have 5 minutes to go.
- 2-minute: Keep up the good work. You have 4 minutes to go.
- 3-minute: You are doing well. You are halfway done.
- 4-minute: Keep up the good work. You have only 2 minutes left.
- 5-minute: You are doing well. You have only 1 minute to go.
- 5:45: In a moment I'm going to tell you to stop. When I do, just stop where you are and I will come to you.

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Study Specific Information: *Provide study-specific information if elements differ between projects.*

Elements that might differ include:

- *Subject and/or study naming conventions*
 - *Compliance requirements*
 - *Account parameters*
 - *Data storage location*
-

Study: [insert study name] *Describe study design, how the device/activity monitor fits within the scope of the study, and what outcomes are specific to the study*

EXAMPLE: “This study is a hypothesis-generating longitudinal cohort study designed to evaluate quality of life, physical activity patterns, and ambulatory blood pressure in patients with thoracic aortic disease.”

I. Test Location

- a. *[List labs, rooms, buildings, etc. where test can and/or will be completed]*

II. Special Notes about This Location

- a. *[Describe any unique requirements about a specific location, e.g. the need for additional staff coverage, the need to bring equipment from off-site, etc.]*

III. Course Description

- a. *[indicate whether feet or meters]*

IV. Data storage

- a. *[List procedures and conventions for data recording and storing of data]*

V. Contacts

- a. *[List contact information for “super users” who are available to help troubleshoot problems. Also include contacts for scheduling, emergencies, etc.]*