

### **SOP 6-Minute-Walk Test**

#### 1. General considerations

The self-paced 6-minute walk test (6MWT) is considered as suitable method to objectively assess the submaximal level of functional exercise capacity in children and adolescents from age 3 on [1, 2]. It measures the distance a participant can walk in a period of 6 minutes (6-minute walking distance/6MWD). Thus it is an easy and inexpensive way to evaluate physical function of an individual and reflects the ability to undertake day-to-day activities. 6MWT will be performed in all participating patients at baseline and at follow up visits according to the corresponding study protocol.

	Definition	Unit
6MWD	<b>6-minute walking distance:</b> covered distance in	
	a quick self-paced walk on a flat, hard surface in a	
	period of 6 minutes	

**Tab.1:** Readout parameter 6MWT.

The following SOP has been adapted from the ATS-guideline on 6-minute walk test ("ATS Statement: Guidelines for Six-Minute Walk Test"). For more detailed information please refer to:

http://www.thoracic.org/statements/resources/pfet/sixminute.pdf

# 2. Contraindications and safety issues

As 6MWT work on submaximal functional capacity and patients determine themselves intensity of their exercise level, 6MWT is considered a safe test procedure. However very few patients may be at increased risk for arrhythmias or cardiovascular events. Therefore the following contraindications (table 2) and safety measures have to be considered. Moreover the test will not be suitable to all patients (ventilated patients, walking disability).

Whether patients with any relative contraindications listed below may perform the test, will be determined by the supervising physician (study center coordinator) based on individual clinical assessment. Any reasons for not performing the test need to be reported.

Absolute Contraindications	Relative Contraindications		
Artificial Ventilation (invasive/non-invasive)	Walking Disability due to neuro-/muscular		
	conditions		
Unstable angina/myocardial infarction in last 4	Severe pulmonary hypertension (suprasystemic		
weeks	PA-pressure)		
	Resting heart rate > 120/min		
	Hypertension diastolic RR > 120 mmHg		
	systolic RR > 180 mmHg		

.Tab.2: Absolute and relative contraindication for 6MWT.

Physicians are not required to be present during all tests. The supervising physician may decide whether physician attendance at a specific test is required.

Technicians must be trained to recognize these adverse/severe adverse events and the appropriate responses (cardiopulmonary resuscitation with a minimum of Basic Life Support) Testing should be performed in a location where a rapid,





appropriate response to an emergency is possible. A crash card with equipment for advanced cardiac life support (including oxygen) must be available.

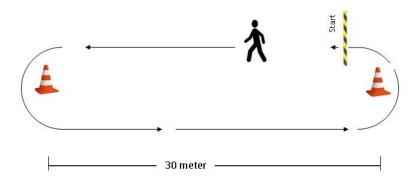
Reasons for immediately stopping a 6MWT include the following: intolerable dyspnea, leg cramps, staggering, diaphoresis, chest pain and/or pale appearance. If a test is stopped for any of these reasons, the patient should sit or lie supine as appropriate.

Any reasons for discontinuing the test need to be reported.

### 3. Test Procedure

## A. Technical aspects

The 6MWT should be performed indoors, along a long, flat, straight, enclosed corridor with a hard surface. The walking course must be 30 m in length. The length of the corridor should be marked every 3 m. The turnaround points are marked with a sign (e.g. traffic cone). A starting line, which marks the beginning and end of each 60-m lap, should be marked on the floor using brightly colored tape (figure 1).



**Fig.1:** Outline of walking course.

**Encouragement** during the test procedure significantly increases the distance walked [3]. Only standardized phrases for instruction and/or encouragement (as specified below) must be used during the test. Technicians who perform 6MWTs should be trained using the standard protocol and then supervised for several tests before performing them alone.

### **B.** Patient specific aspects

Comfortable clothing and appropriate shoes for walking should be worn. Patients should not have exercised vigorously within 2 hours. Patients should use their usual walking aids during the test.

Patients necessitating constant oxygen supplementation should perform the 6MWT under continued oxygen supplementation at usual flow rate. Patient's oxygen tank should not be carried by the patient, but by a technician/helper. This helper should at all times walk *behind* the patient during the test and *avoid verbal or physical encouragement*.





#### C. BORG-Scale

Borg Scale determines the subjective level of exertion in exercise testing. Grade of perceived breathlessness/dyspnoea and fatigue are evaluated by a linear scale (table 3).

At the beginning of the 6-minute exercise, the scale has to be visually shown to the patient (e.g. printed on heavy paper in 20-point type size):

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

And:

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

At the end of the exercise, patients are reminded of the breathing number that they chose before the exercise and asked grade their breathing level again. Then the patient is asked to grade their level of fatigue, after been reminded of their grade before the exercise.

0	Nothing al all	
0,5	Very, very slightly (just noticeable)	
1	very slightly	
2	Slight (light)	
3	moderate	
2 3 4 5 6	Somewhat severe	
5	Severe (heavy)	
6		
7	Very severe	
8		
9		
10	Very, very severe (maximal)	

Tab 3: Borg Scale.

#### D. Measurement

- The patient should sit at rest in a chair, located near the starting position, for at least 10 minutes before the test starts. Check for contraindications and appropriate clothing. Measure pulse, transcutaneous oxygen saturation and blood pressure.
- Have the patient stand and rate their baseline dyspnea and overall fatigue using the Borg scale (see above)
- Instruct the patient as follows:

"The object of this test is to walk as far as possible for 6 minutes. You will walk back and forth in this hallway. Six minutes is a long time to walk, so you will be exerting yourself. You will probably get out of breath or become exhausted. You are permitted to slow down, to stop, and to rest as necessary. You may lean against the wall while resting, but resume walking as soon as you are able. You will be walking back and forth around the cones. You should pivot briskly around the cones and continue back the other way without hesitation. Now I'm going to show you. Please watch the way I turn without hesitation."

Demonstrate by walking one lap yourself. Walk and pivot around a cone briskly. "Are you ready to do that? I am going to use this counter to keep track of the number of laps you complete. I will click it each time you turn around at this starting line. Remember that the object is to walk AS FAR AS POSSIBLE for 6 minutes, but don't run or jog. Start now, or whenever you are ready."





- Position the patient at the starting line. You should also stand near the starting line during the test. Do not walk with the patient. As soon as the patient starts to walk, start the timer.
- Do not talk to anyone during the walk. Use an *even tone* of voice when using the standard phrases of encouragement. Watch the patient. Do not get distracted and lose count of the laps. Each time the participant returns to the starting line, click the lap counter once (or mark the lap on the worksheet). Let the participant see you do it. Exaggerate the click using body language, like using a stopwatch at a race.

After the first minute, tell the patient the following:

"You are doing well. You have 5 minutes to go."

When the timer shows 4 minutes remaining, tell the patient the following: "Keep up the good work. You have 4 minutes to go."

When the timer shows 3 minutes remaining, tell the patient the following: "You are doing well. You are halfway done."

When the timer shows 2 minutes remaining, tell the patient the following: "Keep up the good work. You have 2 minutes to go."

When the timer shows 1 minutes remaining, tell the patient the following: "You are doing well. You have only 1 minute to go."

## Do not use other words of encouragement (or body language).

If the patient stops walking during the test and needs a rest, say this: "You can lean against the wall if you would like; then continue walking whenever you feel able." Do not stop the timer.

If the patient stops before the 6 minutes are up and refuses to continue (or you decide that they should not continue), wheel the chair over for the patient to sit on, discontinue the walk, and note on the worksheet the distance, the time stopped, and the reason for stopping prematurely.

When the timer is 15 seconds from completion, say this:

"In a moment I'm going to tell you to stop. When I do, just stop right where you are and I will come to you."

When the timer rings (or buzzes), say this: "Stop!"

Walk over to the patient. Consider taking the chair if they look exhausted. Mark the spot where they stopped by placing a bean bag or a piece of tape on the floor.

• Post-test: Record the postwalk Borg scale (see above) and ask: "What, if anything, kept you from walking farther?"

Measure SpO, nd pulse rate from the oximeter and then remove the sensor.

- Calculate the total distance walked, rounding to the nearest meter.
- Congratulate the patient on good effort and offer a drink of water.





### 6. Reference Values

In this study data from *Geiger et al.* [1] will serve as age and sex matched reference values.

# 7. Overview of recorded measures

Measure	Unit	
6MWD	m	
transcutaneous oxygen	%	
saturation at rest/after		
exercise		
Heart rate at rest/after	/min	
exercise		
BORG-Scale at rest/after		
exercise		
sex		male/female
age	years	
oxygen supplement		yes/no
Flow rate	I/min	
type		nasal canula/mask
reasons for discontinuation of		free text
test		
reasons for not performing		free text
test		

- 1. Geiger, R., et al., *Six-minute walk test in children and adolescents*. J Pediatr, 2007. **150**(4): p. 395-9, 399 e1-2.
- 2. Li, A.M., et al., Standard reference for the six-minute-walk test in healthy children aged 7 to 16 years. Am J Respir Crit Care Med, 2007. **176**(2): p. 174-80.
- 3. Guyatt, G.H., et al., *Effect of encouragement on walking test performance*. Thorax, 1984. **39**(11): p. 818-22.