



National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
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Procedure No. TEB-CCER-SOP-0616	Revision: 0.0	Date: 7 April 2014
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STANDARD OPERATING PROCEDURE (SOP) FOR HUMAN-SUBJECT WORK RATE (VO_2)
DETERMINATION FOR PERFORMANCE AND CAPACITY TESTING OF CLOSED-CIRCUIT
ESCAPE RESPIRATORS (CCERs)

1. PURPOSE

This procedure provides guidance for performing the method to establish the VO_2 of a human subject for subsequent use in treadmill tests with human subjects of Closed-Circuit Escape Respirators (CCER) submitted for Approval, Extension of Approval, or examined during Certified Product Audits, meet the minimum certification standards set forth in Section 84.304(a)(4) and 84.305(a)(3) of Subpart O—Closed Circuit Escape Respirators updated requirements to 42 CFR, Part 84, Volume 60, Number 110, June 8, 1995 as published in Federal Register / Vol. 77, No. 46 / Thursday, March 8, 2012 / Rules and Regulations pp. 14168-14197.

2. GENERAL

This standard procedure describes measuring VO_2 of a human subject on a treadmill, adjusting treadmill conditions of speed and inclination so that measured VO_2 corresponds to the appropriate value required for either the capacity or performance test for Closed-Circuit Escape Respirators in sufficient detail such that a person knowledgeable in the appropriate technical field can select equipment with the necessary resolution, conduct the determination.

3. EQUIPMENT AND MATERIALS

- 3.1. Gas analyzers with resolution of 0.1% gas concentration, and range of 0-10% CO_2 , and 0-100% O_2
- 3.2. Pressure transducer with resolution of 1 millimeter H_2O , range from -400 to +400 mm H_2O with a digital readout.
- 3.3. Wet and dry-bulb thermometers with resolution of 0.1°C, range 0-100°C
- 3.4. The equipment necessary to perform measurement and calibration is as follows:
 - 3.4.1. One B-D Yale one liter syringe or equivalent
 - 3.4.2. Doric Series 400A Standard Resolution Digital Temperature indicator or equivalent.

Approvals: First Level	Second Level	Third Level	Fourth Level

- 3.4.3. Data recording and display device consisting of a strip chart recorder and/or digital display and data recording software package developed for the metabolic monitoring cart and treadmill system or equivalent.
- 3.4.4. Bench-top electric timer with digital display, calibrated to 100ths (0.01) of a minute (Precision Scientific co.) or equivalent.
- 3.4.5. Digital timer calibrated to 100ths (0.01) of a minute to hand carry or equivalent.
- 3.4.6. AEI Technologies Carbon Dioxide Analyzer Model CD-3A with a range of 0.00-15.00%, and resolution of 0.01% or equivalent. A Beckman LB-2 may be used as an alternate for NIOSH testing.
- 3.4.7. AEI Technologies Oxygen Analyzer Model S3-A/I with a range of 0.00%-100.0%, and a resolution of 0.01% or equivalent. A Beckman Medical Gas Analyzer – OM-11 may be used as an alternate for NIOSH testing.
- 3.4.8. Model 18-49B Horizontal Treadmill, 0-6 MPH, Quinton Instruments, or equivalent.
- 3.4.9. Metabolic cart containing a sampling system that has a relatively large volume (ca. 4L) into which the exhaled air is collected and from which the sample for the gas analyzers is removed. See picture below.



4. PROCEDURE REQUIREMENTS AND CONDITIONS

- 4.1. Test subjects must meet requirements of the NIOSH Human Subject Review Board (HSRB) approved Protocol. Refer to “Protocol for tests with human subjects of closed-circuit breathing apparatus in certification, quality assurance, and development” HSRB

12-NPPTL-04 for the proper consent form and complete details on the use of human test subjects in respirator certification testing.

- 4.2. Prior to beginning any testing, all measuring equipment and instruments to be used must have been calibrated using a method traceable to the National Institute of Standards and Technology (NIST) in accordance with the manufacturer's calibration procedure and schedule.
- 4.3. Normal laboratory safety practices must be observed. These include safety precautions given in the current *NIOSH-Pittsburgh Health and Safety Manual*, Job Hazard Analysis (JHA), work instruction documents and test equipment manufacturer recommended practices.
- 4.4. Any laboratory using this procedure to supply certification test data to NPPTL will be subject to the provisions of the NPPTL Supplier Qualification Program (SQP). This program is based on the tenets of ISO/IEC 17025, the NIOSH Manual of Analytical Methods and other NIOSH guidelines. An initial complete quality system audit and follow on audits are requirements of the Program. Additional details of the Program and its requirements can be obtained directly from NPPTL.)
- 4.5. Refer to “Protocol for tests with human subjects of closed-circuit breathing apparatus in certification, quality assurance, and development” HSRB 12-NPPTL-04 for the consent form and complete details on the use of human test subjects in respirator certification testing.
- 4.6. Procedures will be conducted at the following ambient conditions:
 - 4.6.1. Ambient temperatures of $23^{\circ}\text{C} \pm 3^{\circ}\text{C}$; and
 - 4.6.2. Atmospheric pressures of $735 \text{ mm Hg} \pm 15 \text{ mm Hg}$.

5. PROCEDURES

- 5.1. The gas analyzers should be calibrated using certified calibration gas with O_2 at 80.0 % and CO_2 at 8.0% and N_2 at 12%.
- 5.2. Calibrate pneumotachometer on the metabolic cart using 1-L syringe.
- 5.3. Put assembled T-valve and head harness on human subject and connect exhalation hose to metabolic cart.
- 5.4. Use VO_2 prediction equations for weight of human subject to determine initial speed and grade of treadmill.
 - 5.4.1. For capacity tests the VO_2 should correspond to that in Table 1 below.
 - 5.4.2. For performance tests the VO_2 should correspond to those in Table 2 below.
- 5.5. Have test subject straddle treadmill belt.

- 5.5.1. Have test subject start treadmill belt.
- 5.5.2. Ensure that test subject knows which button stops belt.
- 5.6. Adjust speed and/or grade at preference of human subject to attain target $\dot{V}O_2$.
- 5.7. When $\dot{V}O_2$ target is attained, also note $\dot{V}CO_2$ and V_e from metabolic cart and manually determine RF.
- 5.8. Have test subject stop treadmill after completion of data collection.

Table 1: Capacity Test Requirements

Capacity Rating	Capacity (L)	$\dot{V}O_2$ (L/min)	$\dot{V}CO_2$ (L/min)	V_e (L/min)	RF (Breaths/min)
Cap 1	$20 \leq L \leq 59$	2.50	2.50	55	22
Cap 2	$60 \leq L \leq 79$	2.00	1.80	44	20
Cap 3	$L \geq 80$	1.35	1.15	30	18

$\dot{V}O_2$ = volume of oxygen consumed/min; $\dot{V}CO_2$ = volume of carbon dioxide produced/min
 V_e = ventilation rate; RF = respiratory frequency

Table 2: Performance Test Requirements

Work-Rate Test Sequence	Duration per cycle	$\dot{V}O_2$ (L/min)	$\dot{V}CO_2$ (L/min)	V_e (L/min)	RF (breaths/min)
1. Peak	5 min.	3.00	3.20	65.0	25
2. High	15 min.	2.00	1.80	44.0	20
3. Low	10 min.	0.50	0.40	20.0	12

$\dot{V}O_2$ = volume of oxygen consumed/min; $\dot{V}CO_2$ = volume of carbon dioxide produced/min
 V_e = ventilation rate; RF = respiratory frequency

6. PASS/FAIL CRITERIA

None

7. RECORDS AND TEST SHEETS

7.1. Record test subject identity, $\dot{V}O_2$ target attained and the corresponding treadmill speed and inclination.

7.2. Also record $\dot{V}CO_2$, V_e and RF.

8. ATTACHMENTS

None

Revision History

Revision	Date	Reason for Revision
00	18 August 2011	Initial Record
1.0	29 December 2011	Administrative changes – Document number changed
2.0	09 April 2012	Administrative changes were made to include information from the release of the proposed rule.
		Former document number - STP-00001-PSDB-0010
0.0	7 April 2014	New document number to reflect numbering in the approval library, normalization of format. List of equipment required (section 3) has been updated to reflect those currently employed. Current HSRB requirements are highlighted in section 4. Accessibility enhancements affected. No changes to procedure from historical document.