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Procedure No. TEB-CCER-STP-0604

Revision: 1.0

Date: 5 January 2022

## DETERMINATION OF CAPACITY TEST OF CLOSED-CIRCUIT ESCAPE RESPIRATORS (CCER) AT MANUFACTURER'S RECOMMENDED MINIMUM TEMPERATURE

### 1. PURPOSE

This procedure establishes the test for ensuring that 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 Sections 84.303 and 84.304, of Subpart O—Closed Circuit Escape Respirators updated requirements to 42 CFR Part 84.

### 2. GENERAL

This Standard Testing Procedure (STP) describes the CCER capacity test at the manufacturer's minimum operating temperature, and the equipment, instruments, materials, and minimum performance criteria in sufficient detail such that a person knowledgeable in the appropriate technical field can select equipment with the necessary resolution, conduct the test, and determine whether or not the respirator passes the test.

### 3. EQUIPMENT/MATERIALS

- 3.1. The ABMS instrument and equipment schematic (Figure 1 in the Attachments), includes using a LabVIEW digital display, control, and data recording software.
- 3.2. The following instruments performing stressor measurements should be capable of breath-by-breath responses and have the following measurement ranges:
  - 3.2.1. Carbon dioxide (CO<sub>2</sub>) gas analyzer capable of detecting CO<sub>2</sub> from 0.00 to 15.00 volume %, accurate to within  $\pm 0.02\%$  CO<sub>2</sub>, with a response time of approximately 100 milliseconds and possessing a digital display readout (resolution)  $\pm 0.01\%$  (such as AEI Technologies Carbon Dioxide analyzer Model CD-3A or equivalent)
  - 3.2.2. Oxygen (O<sub>2</sub>) gas analyzer capable of detecting O<sub>2</sub> from 0.00 to 100.00 volume %, accurate to within  $\pm 0.01\%$  O<sub>2</sub>, with a response time of approximately 100 milliseconds and possessing digital display readout (resolution)  $\pm 0.01\%$  (such as AEI Technologies Oxygen analyzer Model S3-A/I or equivalent gas analyzer)
  - 3.2.3. Thermocouple modified to induce evaporative cooling from its tip (thermocouple wire junction point) and capable of measuring a breathing circuit wet bulb temperature ranging from 0 to 100 °C (such as an Omega P/N 5SRTC-TT-T-36-36 Type 'T', 0.005-inch outer diameter thermocouple with appropriate junction point covering)

3.2.4. Pressure transducer capable of measuring breathing circuit breathing resistance from -562.5 to +562.5 mm water (such as a Validyne Model P55D-1-N-2-28-S-4-A or equivalent pressure transducer)

3.3. Support/control instruments and equipment include the following:

3.3.1. Thermocouple capable of breath-by-breath response and measuring a breathing circuit dry bulb temperature ranging from 0 to 100°C (such as an Omega P/N 5SRTC-TT-T-36-36 Type 'T', 0.005-inch outer diameter thermocouple, or equivalent)

3.3.2. Gas sample system electronic moisture removal device, electronic gas chiller capable of lowering the automated breathing and metabolic simulator (ABMS) gas sample system dew point to 3.5 °C, (such as the DEEC Instadryer or equivalent)

3.3.3. CO<sub>2</sub> Mass Flow Controller (MFC) capable of measuring 0-5 LPM (such as the Brooks SLA5850S CO<sub>2</sub>, or equivalent)

3.3.4. N<sub>2</sub> MFC capable of measuring 0-1.7 LPM (such as a Brooks SLA5850S or equivalent)

3.3.4.1. Activated when N<sub>2</sub> flow rates decrease below 1.6 LPM; deactivated when N<sub>2</sub> flow rates increase above 1.7 LPM

3.3.5. N<sub>2</sub> MFC capable of measuring 0-20 LPM (such as a Brooks SLA5850S or equivalent)

3.3.5.1. Activated when N<sub>2</sub> flow rates increase above 1.7 LPM; deactivated when N<sub>2</sub> flow rates decrease below 1.6 LPM

3.3.6. Weigh scale with a 0 to 35,000 mg range with 1 mg scale resolution (such as the Ohaus Ranger R71MHD35 weigh scale or equivalent)

3.3.7. Gas spirometer (such as the Collins P-1700-120 Liter scale gas spirometer or equivalent)

3.3.8. Timer (accurate to 0.01 percent)

3.3.9. Physitemp Thermalert Model TH-8 temperature indicator, or equivalent, with 'T' type thermocouple

3.3.10. Electronic barometric pressure transducer (such as the Vaisala PTU300 electronic barometric pressure transmitter or equivalent)

3.3.11. Environmental chamber (such as the Russells Technical Products Model WMD-288-GCMD-6-6-AC Modular Construction Temperature & Humidity Test Chamber, or equivalent). The ABMS must be located adjacent to the environmental chamber to allow the CCER to be tested while inside the chamber using appropriate means of connection.

3.3.12. BlueStar Color touch screen controller, or equivalent, including data trending, cascade temperature control, ethernet communications capabilities, Windows embedded architecture, user settable deviations alarms with reporting, data exporting capabilities to .csv files, and 90 days data storage.

3.4. Materials required include the following:

3.4.1. Nitrogen (N<sub>2</sub>) Cylinder – At minimum, High Purity grade containing  $\geq 99.99\%$  N<sub>2</sub>

3.4.2. Carbon dioxide cylinder – At minimum, Coleman/Instrument grade containing  $\geq 99.99\%$  CO<sub>2</sub>

3.4.3. Calibration gas traceable to recognized international standards containing 80.0% oxygen, 12.0% nitrogen, and 8.0% carbon dioxide

3.4.4. Phenolphthalein

3.4.5. Deionized water for recirculating water system

4. TESTING REQUIREMENTS AND CONDITIONS

4.1. Prior to beginning any testing, confirm that all measuring equipment and instruments employed have been calibrated in accordance with the testing laboratory’s calibration procedure and schedule. All measuring equipment and instruments must have been calibrated using a method traceable to recognized international standards when available.

4.1.1. Tests will be conducted at an atmospheric pressure of 735 mm Hg  $\pm$  15 mm Hg.

4.1.2. Tests will be conducted at the manufacturer-recommended cold-temperature operating limit specified in the application and provided in the User Instructions (UI).

4.2. Capacity Test Requirements and Conditions

4.2.1. Capacity tests will continuously monitor the stressors listed in Table 1. The stressors will be measured at the interface between the CCER and the ABMS “mouth” by instruments capable of breath-by-breath measurement. Stressor measurements will be evaluated as one-minute averages. The operating (overall) averages of each stressor will be calculated upon the completion of each test as the average of the one-minute measurements of the stressor recorded over the entire test.

4.2.2. Capacity tests will conclude when the stored breathing gas supply has been fully expended or any one-minute average stressor measurement is outside the acceptable excursion range.

4.2.3. The capacity test is conducted at the manufacturer’s recommended minimum operating temperature on two units submitted for approval.

- 4.2.4. Each unit will be tested at a constant work rate, which depends on the capacity specified by the manufacturer, according to the requirements specified in Table 2.

## 5. PROCEDURE

- 5.1. Store the CCER at the manufacturer-recommended minimum temperature.

- 5.1.1. The CCER unit to be tested will be placed inside the environmental chamber.

- 5.1.2. The controlled temperature of the chamber will be adjusted to the manufacturer-recommended cold-temperature operating limit specified in the application and provided in the UI.

- 5.1.3. The CCER unit to be tested will then be maintained in the chamber at the cold temperature limit for at least 24 hours before testing can be started.

- 5.1.4. Just before the capacity test is begun, using care not to activate the unit prematurely, the sample unit will be opened and deployed into the as-worn configuration and then attached to the ABMS.

- 5.1.5. The controlled temperature of the chamber is maintained at the cold temperature limit throughout the capacity test.

- 5.2. Calibrate the O<sub>2</sub> and CO<sub>2</sub> exhaust flows analyzers.

- 5.2.1. Perform ABMS gas analyzer calibration for O<sub>2</sub> and CO<sub>2</sub>.

- 5.2.1.1. Confirm the response times for each gas analyzer are within acceptable ranges as established by the manufacturer.

- 5.2.2. Verify correct waveform for the specific capacity test.

- 5.2.2.1. For a CAP 1 test, set the VO<sub>2</sub> to 2.50 L/min; see Figure 2.

- 5.2.2.2. For a CAP 2 test, set the VO<sub>2</sub> to 2.00 L/min; see Figure 3.

- 5.2.2.3. For a CAP 3 test, set the VO<sub>2</sub> to 1.35 L/min; see Figure 4.

- 5.2.3. Mount the CCER unit on the ABMS trachea and perform a leak check for the ABMS. Ensure all orifices are properly sealed and that the system is leak tight.

- 5.3 Perform the capacity test by selecting the appropriate test protocol to set the corresponding VO<sub>2</sub>, VCO<sub>2</sub>, ventilation rate, and respiratory frequency operating conditions just prior to beginning the simulation operation.

- 5.3.1 The manufacturer's recommended start-up procedure for the CCER being tested must be simulated on the ABMS as closely as possible, as described in the manufacturer UI.

- 5.3.2 Monitor the stressor values in Table 1 throughout the test.

5.3.3 The protocol (work rate) must correspond to the capacity test requirements in Table 2 corresponding to the capacity rating specified by the CCER manufacturer.

5.4 Data Analysis

5.4.1 Calculate the achieved capacity as the product of the completion time (in minutes) and the VO<sub>2</sub> (L/minute) used in the test protocol.

5.4.2 Calculate the overall average for each of the stressor measurements using the one-minute average values from the test start to when the gas supply is fully expended.

5.4.3 Determine the completion time as the time elapsed from test start to when the breathing gas supply is fully expended. Expended breathing gas supply is usually indicated when either the breathing bag is empty, or (if present) the O<sub>2</sub> cylinder is empty, and (as a result) peak inhalation pressure begins to spike below -300 mm H<sub>2</sub>O.

6. PASS/FAIL CRITERIA

6.1. The apparatus fails the test and approval if:

6.1.1. Any average stressor measurement (as the overall average stressor from test start to when the breathing gas supply is fully expended) is outside the acceptable operating average range shown in Table 1 (middle column).

6.1.2. If from the test start up to the completion time any one-minute average stressor measurement is outside the acceptable excursion range shown in Table 1 (last column).

Table 1: Monitored Stressors and their Acceptable Ranges

| Stressor                        | Acceptable Range Operating Average | Acceptable Range Excursion          |
|---------------------------------|------------------------------------|-------------------------------------|
| Average inhaled CO <sub>2</sub> | <1.5%                              | ≤4%                                 |
| Average inhaled O <sub>2</sub>  | >19.5%                             | ≥15%                                |
| Peak Breathing Resistances      | ΔP ≤ 200 mm H <sub>2</sub> O       | -300 ≤ ΔP ≤ 200 mm H <sub>2</sub> O |
| Wet-bulb temperature            | <43°C                              | ≤50°C                               |

6.2 The apparatus fails certification if the achieved capacity is below the minimum capacity indicated for the rating in Table 2.



Table 3: Example Test Summary Data for all CCER Units Submitted for NIOSH Approval

| <b>Device ID</b> | <b>Test</b>                        | <b>Test date</b> | <b>Completion time</b> | <b>Calculated capacity</b> | <b>Indicate minimum capacity</b> | <b>Comments</b> |
|------------------|------------------------------------|------------------|------------------------|----------------------------|----------------------------------|-----------------|
|                  | Capacity at cold temperature limit |                  |                        |                            |                                  |                 |
|                  | Capacity at cold temperature limit |                  |                        |                            |                                  |                 |

8. ATTACHMENTS

- 8.1. Figure 1: Schematic of the ABMS
- 8.2. Figure 2: Graph for CAP 1 Test
- 8.3. Figure 3: Graph for CAP 2 Test
- 8.4. Figure 4: Graph for CAP 3 Test

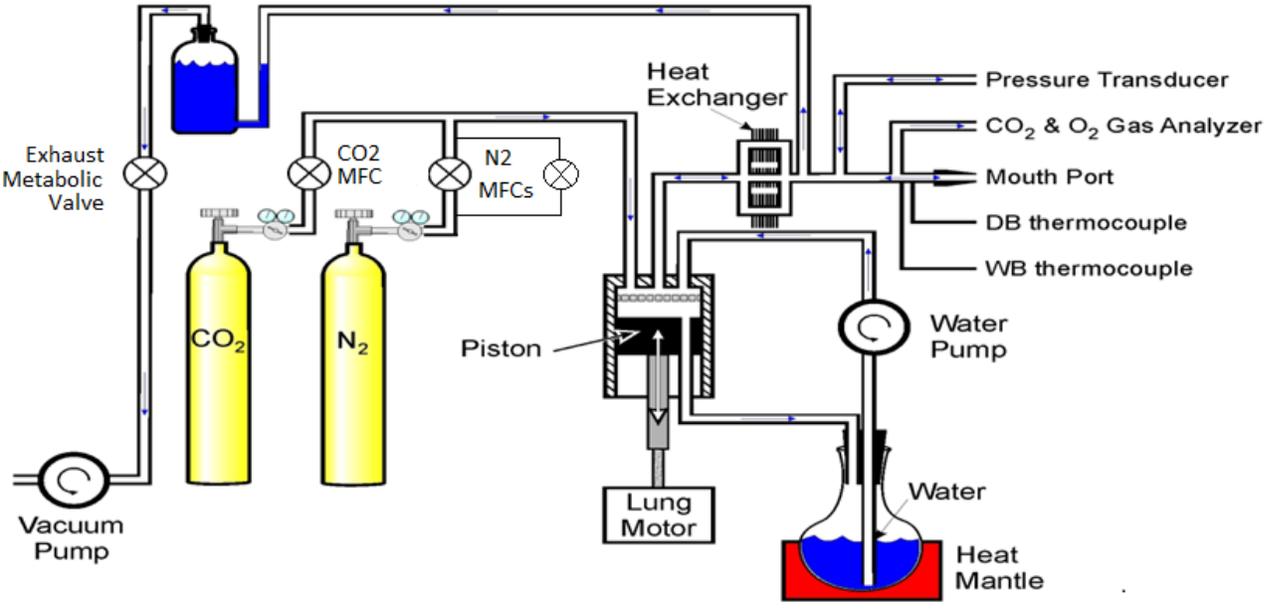


Figure 1: ABMS Schematic

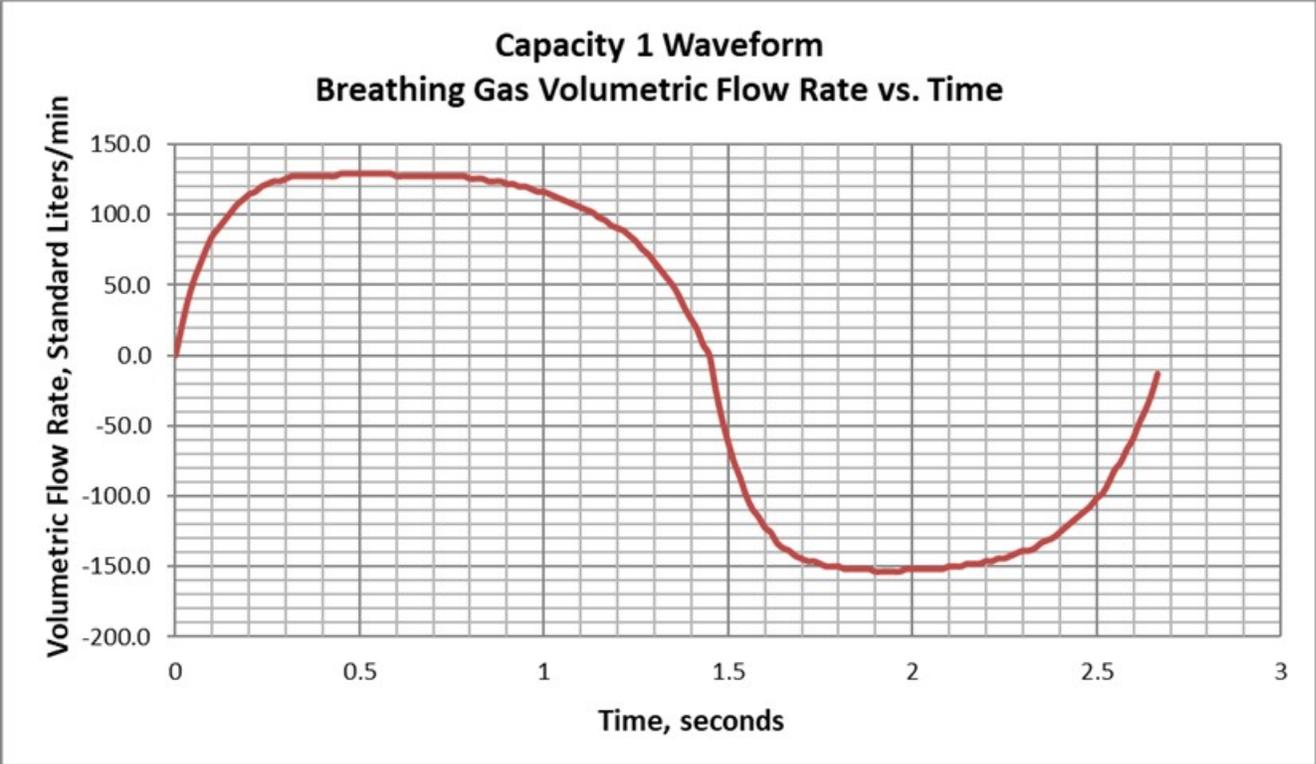


Figure 2. Example graph for CAP 1 Test, showing breathing gas volumetric flow rate (y-axis) vs. time (x-axis)

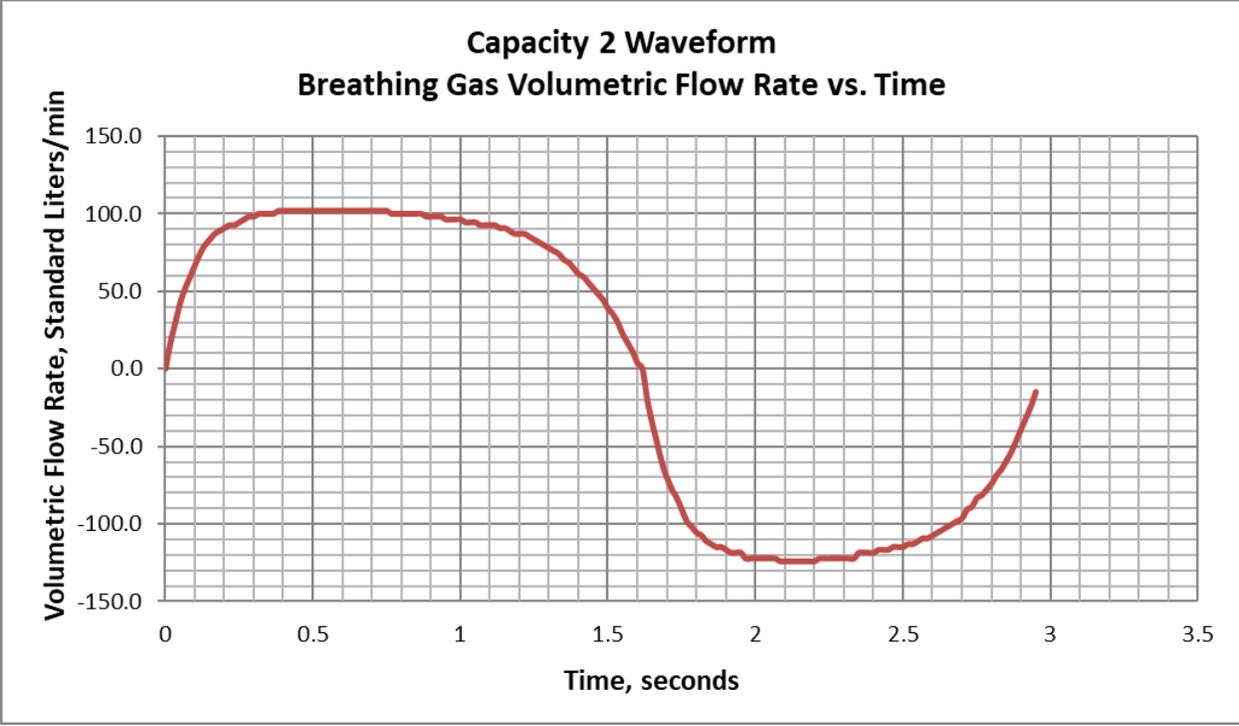


Figure 3: Example graph for CAP 2 Test, showing breathing gas volumetric flow rate (y-axis) vs. time (x-axis).

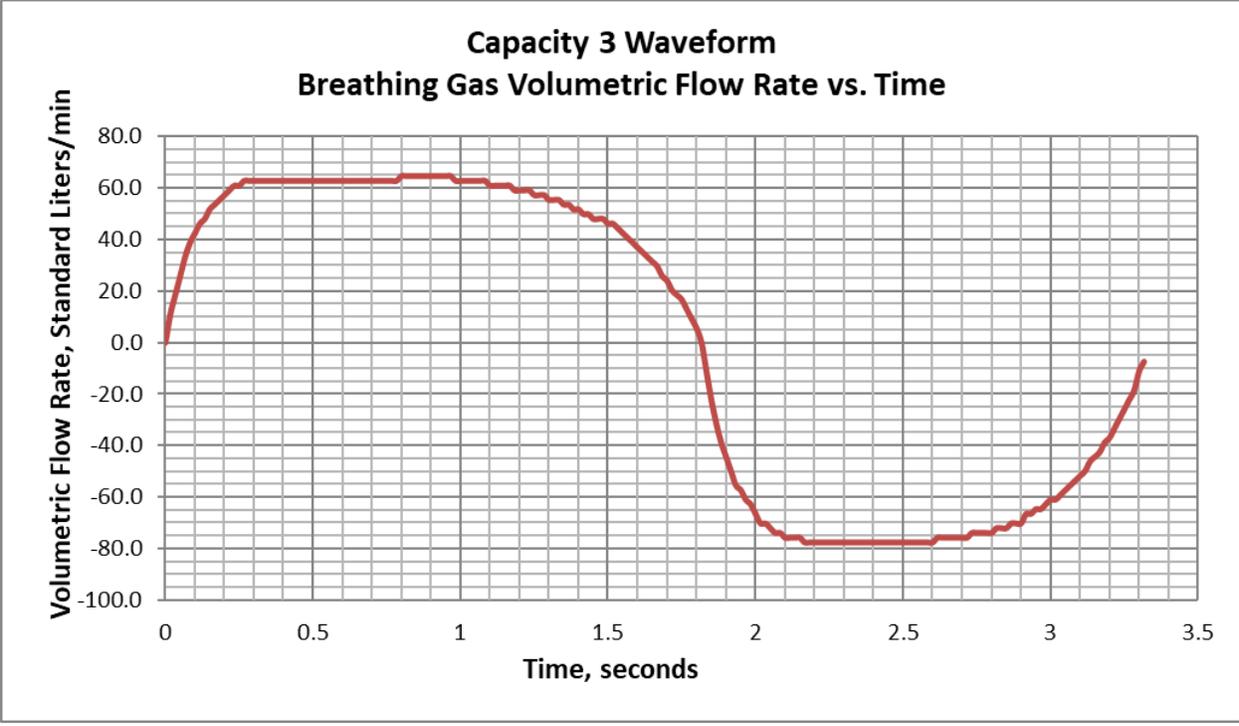


Figure 4: Example graph for CAP 3 Test, showing breathing gas volumetric flow rate (y-axis) vs. time (x-axis).

## Revision History

| <b>Revision</b> | <b>Date</b>      | <b>Reason for Revision</b>   |
|-----------------|------------------|--|
| 00              | 18 August 2011   | Initial Review   |
| 1.0             | 22 December 2011 | Administrative changes – Document number changed   |
| 2.0             | 3 April 2012     | Administrative changes were made to include information for the release of the proposed rule   |
|                 |                  | Former document number - STP-00001-PSDB-0009   |
| 0.1             | 4 April 2014     | New document number to reflect numbering in the approval library, normalization of format. The only changes made in the procedure are in section 5.1. The order of events has been changed to reflect the fact that that the CCER sample will undergo the 24-hour, cold soak in the as-carried (packaged) configuration. Notes have been added at sections 5.2.1. and 5.4.1.1. to clarify termination criteria and data evaluation. The cold operating temperature has been clarified in section 5.1.2. Document accessibility enhancements affected. Other minor grammatical edits have been applied for clarity, but there are no changes to procedure from historical document. |
| 1.0             | 05 January 2022  | Changes were made to the equipment, materials, and the procedure. Examples waveforms were added as Figures.  |