When developing pulmonary function laboratory policies, processes and protocols, it is useful to review the following resources for more information:

- American Thoracic Society/European Respiratory Society (ATS/ERS) Society Standards
- HS4-A2 Application of a Quality Management System Model for Respiratory Services (CLSI, 2006)
- WorkSafeBC Occupational Health and Safety Regulations
- C66-A2 Blood Gas and pH analysis and Related Measurements (CLSI 2009)

Pulmonary Function Process Standards Table of Contents

27.0 Procedure requests
27.1 Procedure requests
27.2 Appropriate information
27.3 Information for patients prior to arrival at the pulmonary function laboratory

28.0 Procedure Manuals
28.1 Documentation
28.2 Relevant information

29.0 Equipment-General
29.1 Selection and installation
29.2 Maintenance and monitoring
29.3 Environmental considerations

30.0 Biologic controls
30.1 Selection and frequency
30.2 Management of biologic control data

31.0 Solutions, medications and supplies
31.1 Inventory control system
31.2 Bronchodilators

32.0 Patient preparation and testing-General
32.1 Patient preparation
32.2 Testing

33.0 Spirometry
33.1 Equipment
33.2 Testing
33.3 Reporting
34.0 Lung Volumes
34.1 Equipment-dilutional testing
34.2 Testing-dilutional testing
34.3 Reporting-dilutional testing
34.4 Equipment-plethysmography
34.5 Testing-plethysmography
34.6 Reporting-plethysmography

35.0 Diffusing Capacity
35.1 Equipment
35.2 Testing
35.3 Reporting

36.0 Maximum Respiratory Pressure
36.1 Equipment
36.2 Testing
36.3 Reporting

37.0 Six Minute Walk
37.1 Testing
37.2 Reporting

38.0 Methacholine Bronchoprovocation
38.1 Equipment
38.2 Testing
38.3 Reporting

39.0 Exercise Induced Bronchospasm
39.1 Equipment
39.2 Testing
39.3 Reporting

40.0 Conductance/Resistance By Body Plethysmography
40.1 Equipment
40.2 Testing
40.3 Reporting

41.0 Arterial Blood Gas
41.1 Sample Collection and Handling
41.2 QC and Proficiency Testing
41.3 Testing
41.4 Reporting

42.0 Reporting-General
42.1 Contents
42.2 Corrected Reports
42.3 Reporting Processes
42.4 Critical Results
43.0 Pulse Oximetry
43.1 Equipment
43.2 Testing

44.0 Overnight Oximetry
44.1 Patient Instructions
44.2 Reporting

45.0 Exercise Testing for the Assessment of Desaturation
45.1 Patient Exclusion Criteria
45.2 Supplemental Oxygen
45.3 Testing
45.4 Reporting

46.0 Cardiopulmonary Exercise Testing
46.1 Patient Exclusion Criteria
46.2 Patient Monitoring
46.3 Testing
46.4 Recording Patient Parameters
46.5 Reporting
27.0 Procedure requests are standardized and ensure that accurate, comprehensive and appropriate information is clearly relayed. (Requests include paper requisitions as well as electronic and verbal requests).

27.1 Processes are in place to ensure the procedure request meets the needs of the laboratory, clients and patients.

27.1.1 Request formats are standardized, unambiguous and easy to follow.
27.1.2 Request format is designed with input from users.
27.1.3 Guidelines for testing are communicated to users of the laboratory.
27.1.4 Guidelines for testing are reviewed and updated as appropriate.
27.1.5 Procedures are only performed when ordered by authorized individuals as defined under relevant legislation.
27.1.6 There is a process to deal with verbal requests.

27.2 Procedure requests contain appropriate information.

27.2.1.0 The request includes relevant clinical and other information including:

27.2.1.1 unique identifiers (patient name, a personal identifier such as PHN or hospital number, birth date, gender).

27.2.1.2 request date.

27.2.1.3 requesting/attending physician.

27.2.1.4 procedure requested.

27.2.1.5 clinical indications for testing.

27.2.1.6 specific instructions or conditions of testing where applicable (e.g. reversible airflow obstruction-omit all bronchodilator).

27.2.1.7.0 Pertinent patient history/patient requirements including:

27.2.1.7.1 smoking history.

27.2.1.7.2 allergies.

27.2.1.7.3 special needs.

27.2.1.7.4 mobility issues.

27.2.1.7.5 current medications.

27.2.1.7.6 infectious diseases if known (e.g. MRSA, TB, SARS).

27.2.1.7.7 surgery.

27.2.1.7.8 associated medical problems (e.g. CHF, MI, previous lung resection etc.).

27.2.1.7.9 translation requirements.

27.2.1.7.10 previous pulmonary function testing.

27.2.2 Additional copies (carbon copy, cc) when appropriate.

27.2.3 Procedure requests indicate urgency.

27.2.4 There is a process in place for clarification of unclear requests, requests that lack the necessary information or requests that contain errors.
ACCREDITATION STANDARDS
PULMONARY FUNCTION TESTING

27.3 Patient preparation instructions are clearly communicated to the patient prior to arriving at the pulmonary function laboratory. (Instructions commonly on the request form).

27.3.1 Patients and/or supporting individuals are advised of patient preparatory instructions prior to the procedure, where appropriate.

27.3.2 Patient instructions are available in a variety of languages considering the population served.

27.3.3.0 Patient Instructions include where appropriate:
27.3.3.1 avoiding alcohol within four hours of testing.
27.3.3.2 avoiding vigorous exercise within 30 minutes of testing.
27.3.3.3 avoiding clothing that substantially restricts full chest and abdominal expansion.
27.3.3.4 avoiding a large meal within two hours of testing.
27.3.3.5 smoking.

27.3.4 Patients are instructed to abstain from medications where appropriate:
27.3.4.1 inhaled bronchodilators, short-acting: 4-8 hours.
27.3.4.2 inhaled bronchodilators, long-acting: 24 hours.
27.3.4.3 anticholinergics: 6 hours.
27.3.4.4 oral short-acting bronchodilators: 8 hours.
27.3.4.5 sustained release beta-agonists: 24 hours.
27.3.4.6 theophylline, twice-daily preparations: 24 hours.
27.3.4.7 theophylline, once-daily preparations: 24 hours.

27.3.5 There are processes to identify and work with patients who do not speak English.

28.0 Procedure manuals are current, accurate, controlled and available.

28.1 The pulmonary function laboratory uses documentation to ensure consistency.

28.1.1 M All procedures are documented and available to staff performing the procedure.
28.1.2 M Documents are reviewed and approved by the medical and technical leaders prior to issue.
28.1.3 Procedures are consistent with the ATS/ERS standards and current literature.
28.1.4 There is evidence of document review at regular intervals.
28.1.5 A written protocol is available that documents the order of testing and important points to cover during testing.
28.1.6 Procedures are performed as documented.
28.1.7 Documentation follows a standardized template.
28.1.8 If documentation is electronic, there are methods to provide procedure details in the event of an information system failure.
28.1.9 There are processes to address the amendment of documents by hand.
28.1.10 Procedural job-aides are dated and associated to the full procedure.
28.2 Procedure manuals contain all the relevant information necessary to perform the procedure such as:

- title.
- purpose or principle.
- policy.
- indications.
- equipment and supplies.
- patient preparation.
- assessment of patients.
- special safety precautions.
- equipment preparation and calibration.
- procedure.
- review and reporting results.
- method limitations.
- procedure notes.
- references.
- appendices and examples.

29.0 Pulmonary function diagnostic equipment is operated, maintained and monitored in a manner that ensures performance specifications are met.

29.1 Pulmonary function equipment is selected and put into operation according to best practices.

- The pulmonary function laboratory uses equipment that meets current ATS/ERS precision and accuracy criteria standards.
- Results of testing on equipment is verified with an appropriate number of controls and compared with existing equipment if applicable.
- Equipment is CSA approved.
- Acceptance testing of equipment is done upon installation of new equipment or new software.
- Equipment is used only as intended by the manufacturer.
- Equipment manufactured for diagnostic testing is used for diagnostic purposes. (Intent: Equipment designed for monitoring should not be used for diagnostic purposes).
- Pulmonary function equipment contains reference equations appropriate to the targeted population.
- Descriptions of equipment are listed in an equipment log including:
  - model.
  - type.
  - age.
  - software version.
  - entry dates for equipment are recorded.
- Equipment that is new, relocated or entering into service after repair, is calibrated, validated, and verified as appropriate, before patient results are reported.
### ACCREDITATION STANDARDS
#### PULMONARY FUNCTION TESTING

**29.2 Pulmonary function equipment is appropriately used, maintained, and monitored.**

- **29.2.1** Equipment is given adequate time to warm up prior to testing (as per manufacturer’s recommendations).
- **29.2.2** Specialized equipment and instrumentation are operated by competent staff with the necessary education, knowledge, skills and certification.
- **M 29.2.3** Documented preventative maintenance, QC and calibration schedules exist.
- **29.2.4** Instructions for maintenance, QC, calibration and monitoring are readily available.
- **29.2.5** Maintenance is performed at regular intervals by appropriately trained staff.
- **29.2.6** QC, installation, service, repair, troubleshooting and maintenance records are readily accessible and retained for the lifetime of the equipment.
- **29.2.7** There is a process to address and resolve issues with equipment when biological and physical controls are outside acceptable limits.
- **29.2.8** When a problem is suspected, calculations are manually performed.
- **29.2.9.0** Pulmonary function equipment is evaluated regularly:
  - **29.2.9.1** quality of tracings/test results.
  - **29.2.9.2** age.
  - **29.2.9.3** safety parameters.
  - **29.2.9.4** software and equipment upgrades.
  - **29.2.9.5** electrical safety inspections are routinely performed by biomedical electronics.

**29.3 Pulmonary function equipment and procedures are operated in suitable environments.**

- **M 29.3.1** Pulmonary diagnostic equipment is calibrated or verified for accuracy and precision. This information is documented and retained.
- **29.3.2** Appropriate environments for the optimal operation of equipment are defined and maintained.
- **29.3.3** Ambient temperature, barometric pressure and relative humidity are monitored.
- **29.3.4** There is a process for corrective action when ambient conditions fall outside of the recommended range.
- **29.3.5** Barometric readings are performed daily.
- **29.3.6** All calibration gases meet manufacturer’s requirements.
- **29.3.7** Gas concentration is monitored where required.
- **29.3.8** Gas pressure is monitored where required.
- **29.3.9** Gas pressure is set according to manufacturer recommendations.
- **29.3.10** Negative air pressure is maintained and monitored where required.
- **M 29.3.11** Internal temperatures of refrigerators storing testing agents or medications are monitored.
- **29.3.12.0** Calibration and other devices are regularly checked and records are maintained:
  - **29.3.12.1** syringes are validated annually.
  - **29.3.12.2** treadmill speeds and grades are calibrated every 3 to 6 months.
  - **29.3.12.3** ergometers are calibrated every 3 to 6 months.
- **29.3.13.0** Dedicated time is made available to perform QC procedures:
  - **29.3.13.1** linearity tests.
  - **29.3.13.2** inhalation challenge delivery devices.
  - **29.3.13.3** leak tests on syringes.
- **M 29.3.14** Equipment is given adequate time to warm up prior to testing (as per manufacturer’s recommendations).
30.0 Biologic controls are used to ensure Quality Control (QC) testing of pulmonary function equipment follows current ATS/ERS standards and best practice.

30.1 Appropriate QC is performed by biologic controls.

<table>
<thead>
<tr>
<th>30.1.1</th>
<th>M</th>
<th>QC policies and procedures for biologic controls are documented and maintained.</th>
</tr>
</thead>
<tbody>
<tr>
<td>30.1.2</td>
<td>M</td>
<td>A biologic control is used to assess and maintain the quality of testing.</td>
</tr>
<tr>
<td>30.1.2.1</td>
<td></td>
<td>Normal lung function (no asthma or other respiratory problems).</td>
</tr>
<tr>
<td>30.1.2.2</td>
<td></td>
<td>Multiple control subjects are regularly used.</td>
</tr>
<tr>
<td>30.1.2.3</td>
<td></td>
<td>Control subjects span a range of values (e.g. a 62” female and a 72” male).</td>
</tr>
<tr>
<td>30.1.2.4</td>
<td></td>
<td>Control testing uses the same protocols as applied to the patient population.</td>
</tr>
<tr>
<td>30.1.2.5</td>
<td></td>
<td>Control measurements meet all criteria for acceptability and repeatability.</td>
</tr>
<tr>
<td>30.1.2.6</td>
<td></td>
<td>Testing is performed at the same time of day to minimize diurnal variation.</td>
</tr>
<tr>
<td>30.1.2.7</td>
<td></td>
<td>If there are multiple pulmonary function systems, controls are tested on each instrument on the same day.</td>
</tr>
</tbody>
</table>

| 30.1.3.0 | | Biological controls are performed at intervals appropriate for the testing modality: |
| 30.1.3.1 | | spirometry – weekly. |
| 30.1.3.2 | | diffusing capacity - bi-weekly. |
| 30.1.3.3 | | plethysmography – monthly. |
| 30.1.3.4 | | nitrogen washout - initially and every 6 months. |
| 30.1.3.5 | | helium dilution - initially and every 6 months. |
| 30.1.4.0 | | Comparability of biologic control data between similar or identical instruments performing the same test is performed and verified at regularly defined intervals. |
| 30.1.4.1 | | QC and patient data from all equipment and analyzers performing the same test are compared on a regular basis and inconsistencies are investigated. |

30.2 Biologic control data is managed to ensure the quality of the pulmonary function laboratory.

| 30.2.1 | M | QC data is recorded and charted in such a way that allows for review and the detection of trends and outliers. |
| 30.2.2 | | QC results and worksheets are reviewed and verified. |
| 30.2.3 | | When QC problems are identified, procedures are implemented to determine cause(s). |
| 30.2.4 | | Roles and responsibilities for QC are well defined. |
| 30.2.5 | | A hierarchy of QC review is established that includes appropriate staff from therapists to medical leaders. |
| 30.2.6 | | Procedures are in place for the appropriate handling of patients while QC problems are investigated. |
| 30.2.7 | | There is a process in place to address QC results that fall outside acceptable criteria. |
| 30.2.8 | M | QC data is collected and submitted to the Diagnostic Accreditation Program of B.C. as required. |
31.0 Solutions, medications and supplies are monitored and handled in a safe way that reduces or eliminates shortages and waste.

31.1 There is an inventory control system in place.
31.1.1 □ Inventory control practices ensure continuity of supply, eliminate shortages, and minimize overstocking and waste.
31.1.2 □ Inventory control problems and actions taken are documented.
31.1.3 □ Receipt and service entry dates of solutions, medications and supplies are recorded as necessary.
31.1.4 □ Expired medications are promptly discarded.
31.1.5 □ Solutions, medications and supplies are labeled, transported and stored appropriately.
31.1.6 □ Policies and procedures address the disbursement or use of solutions and supplies that are recycled or out-dated.
31.1.7 □ There are policies and procedures for the disposal of solutions, medications and supplies where appropriate.
31.1.8 □ There is appropriate and adequate training of staff performing disposal duties.

31.2 Bronchodilators are used in accordance with ATS/ERS standards and best practice.
31.2.1 □ There is a policy to administer a bronchodilator using standardized procedures and techniques.
31.2.2 □ There is a policy and procedure for repeated administration of a bronchodilator.
31.2.3 □ The bronchodilator, dosage and means of delivery are standardized.
31.2.4 □ Spirometry or plethysmography is performed prior to administering the bronchodilator.
31.2.5 □ A spacer is used in conjunction with a meter-dose inhaler (MDI).
31.2.6 □ Post-bronchodilator testing is not performed until 15 minutes after administration of the bronchodilator.
32.0 Pulmonary function patient preparation and testing is performed according to current ATS/ERS standards and best practices. (NB These criteria and descriptors apply to the specific testing listed in 33.0 - 41.0).

32.1 Procedure preparation is delivered in a manner that meets patient needs and test requirements.

- **32.1.1** M □ There is a process in place to ensure positive patient identification.
- **32.1.2** M □ Patient exclusion criteria have been established.
- **32.1.3** M □ Staff are aware of exclusion criteria.
- **32.1.4** □ Detailed patient histories are obtained when appropriate.
- **32.1.5** □ There are processes in place to ensure that patients have followed the preparation instructions.
- **32.1.6** □ Indications and contraindications for testing are documented and available to staff.
- **32.1.7** □ There are processes to deal with borderline contraindications.
- **32.1.8.0** □ Patients are assessed for contraindications for the procedure or other exclusion criteria:
  - **32.1.8.1** □ consuming alcohol.
  - **32.1.8.2** □ performing vigorous exercise.
  - **32.1.8.3** □ wearing clothing that substantially restricts full chest and abdominal expansion.
  - **32.1.8.4** □ eating a large meal.
  - **32.1.8.5** □ smoking.
  - **32.1.8.6** □ non-compliance in withholding medication.
- **32.1.9.0** □ Other factors that affect the test are documented and considered including:
  - **32.1.9.1** □ anemia.
  - **32.1.9.2** □ polycythemia.
  - **32.1.9.3** □ diurnal variation (if serial measurements are anticipated, the time of day is kept the same).
  - **32.1.9.4** □ claustrophobia.
  - **32.1.9.5** □ morbid obesity.
  - **32.1.9.6** □ heavy exercise prior to testing.
- **32.1.10** □ The patient’s physical and developmental status to undergo the diagnostic test is assessed to determine if special arrangements are required.
- **32.1.11** □ If postponement is necessary the ordering physician is contacted to determine if rescheduling is necessary.
- **32.1.12** □ If the ordering physician cannot be contacted, the laboratory medical leader or designate determines if testing should proceed.
- **32.1.13** □ There are processes that address instances when there is deviation from the protocol.
- **32.1.14** □ There are procedures to identify possible communicable diseases prior to the procedure.
- **32.1.15** □ The patient’s height and weight are determined and recorded.
- **32.1.16** □ There is a process to obtain height and weight when patients are unable to stand or when there is a spinal deformity.
- **32.1.17** □ Race is recorded and considered in the selection of reference values and interpretation of the results.
- **32.1.18** □ When appropriate, procedures are in place for patients receiving supplemental oxygen.
32.2 Testing is performed according to best practice.

32.2.1 M ☐ Staff performing test are aware of indications for immediately stopping test.
32.2.2 M ☐ The test is explained and demonstrated to the patient just prior to the procedure.
32.2.3 ☐ Patient positioning is assessed and corrected if necessary.
32.2.4 ☐ Nose clips are used and checked for correct positioning (excluding 6 minute walk testing).
32.2.5 M ☐ During the procedure the therapist appropriately coaches the patient.
32.2.6 ☐ Patients are monitored during testing where appropriate.
32.2.7 M ☐ The patient is observed during the procedure.
32.2.8 ☐ Time interval between repeated tests is in compliance with ATS/ERS standards.
32.2.9 ☐ Post-bronchodilation testing is not performed for 15 minutes after the bronchodilator is given.
32.2.10 ☐ Reversibility testing follows ATS/ERS standards.
32.2.11 ☐ Patients and or caregivers are given instructions on post-procedural care when warranted (e.g. after blood gases, methacholine and exercise testing).

33.0 Spirometry is performed according to current ATS/ERS standards and best practices.

33.1 Calibration of spirometry equipment follows current ATS/ERS standards and best practices.

33.1.1 ☐ Calibration syringes are maintained at the same temperature and humidity as spirometers.
33.1.2 ☐ Calibration or calibration verification is performed every day of patient testing.
33.1.3 ☐ Calibration checks on flow measuring devices include flow ranges between 0.5 and 12 L/sec.
33.1.4 ☐ Recalibration is performed if temperature changes 2°C or relative humidity changes 5%.
33.1.5.0 ☐ Calibration checks are repeated as appropriate:
33.1.5.1 ☐ when large numbers of patients are tested.
33.1.5.2 ☐ there is a change in environmental conditions.
33.1.5.3 ☐ a problem is suspected with equipment.
33.1.6 ☐ A log of calibration checks is maintained.
33.1.7 ☐ Calibration syringes are leak tested regularly, and volume is verified and recalibrated annually.
33.1.8 ☐ Calibration checks are performed when equipment is changed or relocated.
33.1.9 ☐ Calibration checks are performed with the filter in line, if filters are used during patient testing.
33.2 The performance of spirometry follows current ATS/ERS standards and best practices.

33.2.0 The test is explained and demonstrated to the subject prior to the procedure:

- correct posture with head slightly elevated.
- position of the mouthpiece.
- exhale with maximal force.

33.2.1 Testing is done in a chair with arms and no wheels.

33.2.2 Nose clips are used and checked for correct positioning.

33.2.3 Inspiration is rapid and full.

33.2.4 Three acceptable FVC maneuvers are obtained.

33.2.5 After eight maneuvers a clinical judgment to stop or proceed is made, as per defined laboratory practice.

33.2.7 Acceptability and repeatability criteria are well-defined:

- the start of the FVC maneuver is fast and unhesitating, with back extrapolation of less than 5% of the FVC or 0.15 L, whichever is greater.
- no coughing during the first second of an FVC maneuver.
- no glottis closure that influences the measurement.
- a plateau of one second is achieved with no change in volume in the volume-time spirogram and a duration of six seconds in the volume-time curve.
- a minimum of three acceptable full efforts are recorded with the two largest values (FVC, FEV1) agreeing within 150 mL.
- If FVC, FEV1 are less than 1L, then agreement is within 100mL.
33.3 The reporting of spirometry results follows current ATS/ERS standards and best practices.

33.3.1 All volumes and flows are reported at body temperature and pressure saturated with water vapor (BTPS) conditions.

33.3.2 The largest VC from at least two acceptable maneuvers is reported; the same value is used for lung volume calculations.

33.3.3 The largest FVC and largest FEV₁ from acceptable maneuvers are reported, even though the values may not come from the same maneuver.

33.3.4 The largest PEF obtained is reported.

33.3.5 All other flows (e.g., FEF₂₅-₇₅%, FEF₅₀%) are reported from the “best” test. The “best” test is defined as the maneuver with the largest sum of FVC and FEV₁.

33.3.6 All inspiratory measurements (e.g., FIVC, PIF, and FIF₅₀%) are the largest values obtained.

33.3.7 If a single volume-time tracing or flow-volume curve is included in the final report, it is the spirogram from the effort with the largest sum of FVC and FEV₁.

33.3.8 Expiratory and inspiratory flow-volume curves from different acceptable efforts may be combined to produce a flow-volume loop. Laboratories are strongly encouraged to print (display) at least three acceptable maneuvers.

33.3.9 If reporting, the highest acceptable MVV (L/min) and MVV rate (breaths/min) are used.

33.3.10 Volume versus time tracings from at least two acceptable maneuvers are retained and available.

33.3.11 Therapist’s comments on patient effort and cooperation, and/or grading scores or codes regarding the acceptability and repeatability of the data are reported.

33.3.12 The instrument’s software version is reported.

33.3.13 Date, time, and results of most recent calibration are reported.

33.3.14 The reference values used are reported.
34.0 Lung volume testing is performed according to current ATS/ERS standards and best practices.

34.1 Equipment preparation and calibration for dilutional lung volume testing follows current ATS/ERS standards and best practices.

34.1.1 The system is checked daily to ensure it is leak-free.
34.1.2 Volume calibration (verification) is performed at least once each day testing is performed using a calibrated 3L syringe.
34.1.3 The accuracy validation limit for recovered volume is ±3.5% of the standard. (e.g. for a 3.0 L calibrated syringe, the recovered volume is between 2.9 L and 3.1 L).
34.1.4 Recalibration is performed if temperature changes 2° C or relative humidity changes 5%.
34.1.5.0 For a nitrogen washout system:
   34.1.5.1 a 100% O₂ gas source is available for a 10 minute (minimum) test.
   34.1.5.2 the demand valve allows adequate flow with minimal resistance.
   34.1.5.3 a three point calibration is performed prior to each procedure on systems using a nitrogen washout method.
34.1.6.0 For a helium dilution system:
   34.1.6.1 CO₂ and water (H₂O) absorbers are fresh (replace according to manufacturer’s recommendations) and placed in the proper order.
   34.1.6.2 the fan (to mix and circulate gases) is operational.
34.1.7 Two-point (zero to full scale) calibration of the He analyzer is performed at least once each day prior to testing patients.
34.1.8 A lung analog (calibrated syringe or similar device) test is performed at least monthly on systems using the He dilution and N2 washout methods.
34.2 Measurement of dilutional lung volume testing follows current ATS/ERS standards and best practices.

34.2.1 There is a process to address patients with severe COPD factors undergoing multiple-breath dilution or washout methods.

34.2.2 The patient is seated upright. If another position is used, it is noted.

34.2.3 When appropriate, earplugs are provided for patients with perforated eardrums.

34.2.4 The facility has a process that dictates at what point during the procedure slow vital capacity maneuvers are performed.

34.2.5.0 For a nitrogen washout system:

34.2.5.1 If nitrogen washout is to be performed, the patient should not have supplemental \( O_2 \) for at least 15 minutes.

34.2.5.2 There are processes to deal with patients with very severe lung disease or hypoxemia when discontinuation of supplemental \( O_2 \) is contraindicated.

34.2.5.3 Test completion is identified as a nitrogen concentration of less than 1.5% for three successive breaths.

34.2.5.4 If more than one nitrogen washout test is performed, then there is a 15 minute interval between tests.

34.2.6.0 For a helium dilution system:

34.2.6.1 The fan (to mix and circulate gases) is operational.

34.2.6.2 Only 1 FRC is performed in helium dilution. Note: only one acceptable FRC maneuver is required.

34.2.6.3 Test completion is defined as a helium concentration within 0.02% for 30 seconds (helium dilution).

34.2.6.4 If more than one FRC\( _{He} \) is performed, then there is at least a 5 minute interval between tests, and the repeatability is within 10%. The 5 minute interval between tests may be extended if maldistribution of gas is present.

34.3 The reporting of dilutional lung volume testing follows current ATS/ERS standards and best practices.

34.3.1 The mean Functional Residual Capacity (FRC) is reported when multiple acceptable trials are performed.

34.3.2 The method for calculating and reporting TLC is defined.

34.3.3 The largest VC is reported.
34.4 Equipment preparation and calibration for lung volume testing by plethysmography follows current ATS/ERS standards and best practices.

- Volume calibration (verification) is performed at least once each day testing is performed using a calibrated 3L syringe.
- The accuracy validation limit for recovered volume is ±3.5% of the standard (e.g. for a 3.0 L calibrated syringe, the recovered volume is between 2.9 L and 3.1 L.).
- Recalibration is performed if temperature changes 2° C or relative humidity changes 5%.
- The mouth occlusion shutter has minimal resistance to opening and closing (i.e. the shutter does not stick).
- Pressure transducers are correctly aligned.
- The door seal is adequate.
- An isothermal lung simulator is used at least monthly to verify volume accuracy for plethysmography methods.
- Calibration of mouth pressure and box pressure transducers is performed:
  - once each day prior to testing patients.
  - every 4 hours during testing.

34.5 Measurement of lung volume testing by plethysmography follows current ATS/ERS standards and best practices.

- There are processes to address factors that limit the patient’s access into the chamber:
  - claustrophobia.
  - upper body paralysis.
  - obtrusive casts.
  - other factors.
- The patient is seated upright. If another position is used, it is noted.
- Baseline and panting maneuvers are well defined.
- The facility has a process that dictates at what point during the procedure slow vital capacity maneuvers are performed.
- Staff edits VTG slopes as appropriate.

34.6 The reporting of lung volume testing by plethysmography follows current ATS/ERS standards and best practices.

- The mean Functional Residual Capacity (FRC) is reported.
- The mean FRC is reported if more than two tests are performed with results agreeing within 5% (Plethysmography).
- The method for reporting IC, ERV and TLC is defined with linked methods preferred.
- The largest VC is reported.
- Therapist’s quality statements are used to clarify which method was used for reporting IC or ERV and the reasons for selecting the method (e.g., “Patient had difficulty providing consistent ERV values, but IC was highly repeatable”).
35.0 Diffusing capacity testing is performed according to current ATS/ERS standards and best practices.

35.1 Equipment preparation and calibration for Diffusing Capacity (DLCO) testing follows current ATS/ERS standards and best practices.

35.1.1 ☐ The cylinder(s) of test gas are appropriate for the testing system.
35.1.2 ☐ The system is checked to ensure it is leak-free daily.
35.1.3 ☐ Gas conditioning devices are changed as per manufacturer’s recommendations (i.e. gas chromatograph columns, permeable tubing, CO₂ and H₂O absorbers).
35.1.4 ☐ All devices maintain the required volume accuracy regardless of the gas mixture.
35.1.5 ☐ Linearity of analyzers is maintained and verified.
35.1.6 ☐ Non linearity of the analyzers does not exceed 0.5%.
35.1.7 ☐ A calibration check (verification) with a validated known-volume syringe (e.g. 3.0 L) is performed each day of testing. The accuracy validation limit for recovered volume is ±3.5%.
35.1.8 ☐ For large surveys or high patient loads this volume calibration check is done more frequently.
35.1.9 ☐ A two-point (zero and full scale) calibration of the gas analyzer(s) is done just prior to testing each patient.
35.1.10 ☐ Testing systems are checked with a DLCO simulator.
35.2 The measurement of diffusing capacity (DLCO) and results review follows current ATS/ERS standards and best practices.

35.2.1.0 The patient is asked if they have complied with preparation criteria and have:
35.2.1.1.1 The time of the last cigarette smoked is recorded.
35.2.1.2.1 refrained from smoking on the day of testing.
35.2.1.1.2 A correction for CO back-pressure is made for recent or heavy smoking, as defined by laboratory procedures.
35.2.1.2.2 refrained from heavy exercise immediately prior to testing.
35.2.1.2.3 refrained from eating a large meal at least 2 hours prior to testing.
35.2.1.2.4 refrained from drinking alcohol for 4 hours prior to testing.

35.2.2 Mouthpiece, nose clip, carbon dioxide (CO₂) and water absorbers, and other miscellaneous supplies (e.g., tissues, chart paper) are available as needed.

35.2.3 Infection control supplies: disposable in-line filters (if used), gloves, gowns, masks, and protective eye wear (if applicable) are available as needed.

35.2.4 Testing is done in the sitting position, with the patient sitting quietly for a minimum of 5 minutes before testing.

35.2.5 No supplemental oxygen is given for 10 minutes preceding the test if possible.

35.2.6 There are mechanisms to recognize patients with mental confusion or poor muscular coordination that prevent the patient from adequately performing the maneuver or the inability to adequately seal their lips on the instrument mouthpiece.

35.2.7.0 Acceptability criteria for individual test maneuvers are defined:
35.2.7.1 inspired volume of test gas is at least 85% of the largest VC in less than 3 seconds.

35.2.8.0 The breath time hold (Jones-Mead technique) is 8-12 seconds.
35.2.8.1 No evidence of leaks or Valsalva or Mueller maneuvers during breath hold.
35.2.8.2 Expiration after breath hold in less than 4 seconds with appropriate clearance of dead space before sampling the alveolar gas.
35.2.8.3 The washout volume of anatomical and mechanical dead space is 0.75 to 1.0 L before the alveolar sample is collected.

35.2.9 There are at least 4 minutes between maneuvers.

35.2.10 There are two acceptable maneuvers that agree within 3 mL CO/min/mmHg or within 10% of the highest value.

35.2.11 No more than 5 maneuvers are performed.

35.2.12.0 Significant discrepancies are recorded:
35.2.12.1 when inspired volume is less than 85% vital capacity.
35.2.12.2 when alveolar volume is greater than total lung capacity.
35.3  The reporting of DLCO testing follows current ATS/ERS standards and best practices.

35.3.1  The average of at least two acceptable maneuvers that meet the repeatability requirement are reported.

35.3.2.0  The report includes:

35.3.2.1  measured, uncorrected DLCO.
35.3.2.2  predicted DLCO.
35.3.2.3  percent predicted DLCO.
35.3.2.4  DLCO/VA (also known as KCO).
35.3.2.5  VA and IVC.

35.3.3  Any adjustments (e.g., Hb, COHb, PO2) are reported separately along with the data used to make the adjustment.

35.3.4  There is a procedure for adjustment of sampling windows in real time analyzers.

35.3.5  The reason for adjusting the sampling window is documented.

36.0  Maximum respiratory pressure testing is performed according to current ATS/ERS standards and best practices.

36.1  Maximum Respiratory Pressures testing and results review follows current ATS/ERS standards and best practices.

36.1.1  PEmax is measured at or near total lung capacity (TLC).

36.1.2  PImax is measured near residual volume (RV).

36.2  The reporting of Maximum Respiratory Pressure testing follows current ATS/ERS standards and best practices.

36.2.1  The most negative PImax in cmH2O that can be sustained for 1.0 to 1.5 seconds is reported.

36.2.2  The most positive PEmax in cmH2O that can be sustained for 1.0 to 1.5 seconds is reported.

36.2.3  The number of efforts, degree of repeatability, percent of predicted, and lower limit of normal are reported.

36.2.4  Pressures are presented as percent of predicted TLC at which they were measured to adjust for differences in body size and varied levels of lung capacity, caused by disease states.
37.0 Six minute walk testing is performed according to current ATS/ERS standards and best practices.

37.1 Six minute walk testing follows current ATS/ERS standards and best practices.

37.1.1 The test is performed indoors, along a flat, long, straight, corridor with a hard surface with little traffic.

37.1.2 The walking course is approximately 30 meters (100 feet) in length.

37.1.3 The course is marked with visible markers (e.g., traffic cones).

37.1.4 A starting line, which marks the beginning and end of each 60 metre lap, is marked on the floor.

37.1.5 Incremental distance markers are used (e.g., every 10 metres) to help measure the distance walked.

37.1.6 A stopwatch is used to time the test.

37.1.7 A mechanical counter is used to count laps.

37.1.8 Blood pressure, heart rate and Borg dyspnea scale results are recorded prior to the test.

37.1.9 Procedures are explained and/or demonstrated to patients.

37.1.10 Patients use their usual walking aids during the test (cane, walker etc.).

37.1.11 Procedural sources of variability are controlled as much as possible, (including the use of standard phrases).

37.1.12 Patients wear loose-fitting, comfortable clothing and shoes suitable for exercise.

37.1.13 The results from a resting ECG done during the previous 6 months is reviewed.

37.1.14 Continuation of patient medications is addressed.

37.1.15 Patients with stable, exertional angina will perform the test with anti-angina medication.

37.1.16 Supplemental oxygen is continued unless otherwise indicated.

37.1.17 Staff has appropriate training to support the patient:

   (Basic Life Support - minimum, ACLS preferred).

37.1.18 There is a process in place to remove supplemental oxygen if indicated.

37.1.19 Testing is performed in a location where a rapid emergency response is possible.

37.1.20 A telephone or other means is available to call for help.

37.1.21 A medical doctor with a rapid response time is available on-site.

37.1.22 Procedures and equipment are available to deal with acute adverse events.

37.2 The reporting of six minute walk testing follows current ATS/ERS standards and best practices.

37.2.1 Reports contain the following:

37.2.1.0 the total distance walked.

37.2.1.1 oxygen use if applicable.

37.2.1.2 litre flow (e.g. continuous or pushed).

37.2.1.3 delivery device (e.g. nasal cannula, oxygen pendant).

37.2.1.4 mode of transport (e.g. carried or pushed/pulled).

37.2.1.5 Borg scale.

37.2.2 reason for early termination if applicable.
38.0 Methacholine bronchoprovocation testing is performed according to current ATS/ERS standards and best practices.

38.1 Equipment preparation and calibration for methacholine bronchoprovocation testing follows current ATS/ERS standards and best practices.

38.1.1 Methacholine is stored at 4° - 8° C and warmed to room temperature prior to patient use.

38.1.2 The nebulizer and compressed gas systems are checked to ensure they are working properly.

38.1.3 The pulmonary function testing system is calibrated each day of use and before the challenge.

38.1.4 The testing area is large enough to accommodate equipment, personnel and emergencies.

38.1.5 The testing room has adequate ventilation (i.e., at least two air exchanges/hour).

38.1.6 Exhalation filters are used on nebulizers to minimize the chance that the therapist will be exposed to the methacholine aerosol.

38.1.7.0 Procedures, medications and equipment are available to deal with acute adverse events including:

38.1.7.1 M ☐ oxygen and appropriate delivery devices, a stethoscope, a sphygmomanometer and a pulse oximeter.

38.1.7.2 M ☐ medications to treat an acute bronchospasm attack including epinephrine for subcutaneous injection, and albuterol and ipratropium bromide in either metered dose inhaler and/or premixed solutions.

38.1.8 M ☐ a medical doctor experienced in acute bronchospasm reversibility on-site.


**ACCREDITATION STANDARDS**

**PULMONARY FUNCTION TESTING**

38.2 Methacholine bronchoprovocation challenge testing follows current ATS/ERS standards and best practices.

38.2.1.0 The laboratory has established criteria for withholding medications from patients:

- short-acting inhaled bronchodilators (e.g., albuterol): 8 hours.
- long-acting inhaled bronchodilators (e.g., salmeterol): 48 hours.
- anticholinergics: 24 hours, or as defined by the laboratory.
- cromolyn sodium: 8 hours.
- nedocromil: 48 hours.
- liquid theophylline: 12 hours.
- intermediate-acting theophylline: 24 hours.
- long-acting theophylline: 48 hours.
- leukotriene modifiers: 24 hours.
- corticosteroids: Not usually withheld, or withheld only on day of test.

38.2.1.1 Patients are given instructions as to which medications/items to avoid prior to testing.

38.2.3 A screening spirometry test with pre and post bronchodilator maneuvers is performed prior to a methacholine challenge test.

38.2.4 Procedures are explained to patients and consent forms are obtained.

38.2.5 Therapists are familiar with safety and emergency procedures.

38.2.6 Aerosolized methacholine exposure is minimized when staff have asthma or symptoms suggestive of hyper-reactive airways.

38.2.7 Therapists who perform methacholine challenges have a negative methacholine challenge at entry.

38.2.8 Dosing protocols are in compliance with ATS/ERS standards.

38.2.9 Signs and symptoms of acute bronchospasm are recorded.

38.2.10 The time interval between methacholine doses does not exceed five minutes.

38.2.11 Criteria are clearly defined for the end of a methacholine challenge test.

38.2.12 A bronchodilator is administered (if applicable) and post-bronchodilator spirometry performed, and FEV₁ at least 90% of baseline.

38.2.13 Patients are not released until post-test values are within 10% of pre-test values.

38.2.14.0 When shortening the test procedure, a two-fold increase in methacholine dose is used for the following patients:

- a child.
- a patient known to have moderate to severe asthma.
- a patient with airflow obstruction on baseline spirometry.
- in patients where the FEV₁ fell by more than 10% after the previous methacholine dose.

38.2.15 The laboratory has a defined quality assurance process in place for methacholine dosing, dilution, and labeling of specific concentration containers.
38.3 The test results review and reporting of methacholine bronchoprovocation testing follows current ATS/ERS standards and best practices.

38.3.1 Assure acceptable and repeatable spirometry data at baseline and/or control (post-diluent) stages.

38.3.2.0 Assure at least two acceptable spirometry trials are performed at each stage.

38.3.2.1 Repeatability of FEV₁ (i.e., two highest within 150 mL) if possible.

38.3.3 Data is expressed as a percent of baseline or the post-diluent value.

38.3.4 If more than one diluent stage is used, the percent change is calculated from the final post-diluent stage.

38.3.5 Data is presented for each step in the protocol, including bronchodilator reversal.

38.3.6 The FVC, FEV₁, and FEV₁/FVC ratio (if complete FVC maneuvers were performed) are reported for spirometry.

38.3.7 The specific conductance (sGaw) or specific resistance (sRaw) is reported for plethysmography measurements.

38.3.8 The dose is expressed as mg/mL concentration of inhaled methacholine.

38.3.9 Graphic and tabular displays showing percent change and absolute values are presented in the report.

38.3.10 Therapist comments include evaluations of patient effort and cooperation, whether coughing occurs, and patient response to specific queries concerning the presence of shortness of breath, wheezing, and other symptoms that can be used to confirm the response.

38.3.11 The concentration that caused a 20% fall in FEV₁ (PC₂₀) in mg/mL is reported.

38.3.12 If sGaw or sRaw is measured, the concentration that causes a 40% fall in sGaw or a 40% rise in sRaw is reported.
39.0 Exercise-induced bronchospasm testing is performed according to current ATS/ERS standards and best practices.

39.1 Equipment used for exercise-induced bronchospasm testing follows current ATS/ERS standards and best practices.

- Treadmills are in compliance with ATS/ERS standards.
- Speed range 0 to 8 mph.
- Grade range 0 to 20%.
- Emergency stop button.
- Padded hand rails (front and sides).
- ECG system meets American Heart Association specifications:
  - Continuous oscilloscopic monitoring of a minimum of three leads.
  - 12-lead printed-copy capacity.
- The testing area is large enough to accommodate equipment, personnel and emergencies.
- O₂ and appropriate O₂ delivery devices, a stethoscope and sphygmomanometer to auscultate the chest and to measure blood pressure, and a pulse oximeter to ensure adequate O₂ delivery are readily available.
- A medical doctor experienced in acute bronchospasm reversibility is present on-site.
- Procedures, medications and equipment are available to deal with acute adverse events:
  - Airway management equipment.
  - Defibrillator.
  - Suction.
  - Emergency medications (e.g. epinephrine and lidocaine).
  - Bronchodilators.
  - Oxygen equipment and delivery systems.
  - Airway management equipment.
- The resuscitation cart is checked regularly:
  - An inventory checklist accompanies the cart.
  - The cart is checked daily or weekly (according to institution policy) for missing or outdated medications.
- The operation of airway-management equipment is checked.
- Staff performing testing are able to recognize basic ECG arrhythmias.
- Staff performing testing are trained in advanced cardiac life support and certified to perform CPR.
- The absolute water content of the inspired air is below 10 mg/L or relative humidity (RH) less than 50% between 20° and 25° C when appropriate.
- A dry gas source (e.g., compressed air cylinder) with reservoir bag, valves and tubing, or demand valve is used if not using room air.
- A cold-air generating device is used when the patient’s complaints specifically relate to symptoms by cold air inhalation when appropriate.
39.2 Exercise-induced bronchospasm testing follows best current ATS/ERS standards and best practices.

39.2.1 Patients are evaluated for their ability to perform exercise-induced bronchospasm testing.
39.2.2 The patient’s medical history is reviewed by a trained physician.
39.2.3 Past ECGs are obtained and reviewed when available.
39.2.4 ECG monitoring is used when appropriate.
39.2.5 Procedures are explained to patients and consent forms are obtained as appropriate.
39.2.6 Equations to predict the maximum heart rate are documented.
39.2.7 The patient exercises at a moderate to heavy intensity level for approximately 6 to 8 minutes.
39.2.8 Two or three acceptable spirometry tests are obtained at each testing interval.
39.2.9 If EIB is documented by pulmonary function testing, a bronchodilator is administered as needed.
39.2.10 The indications for stopping an exercise test are documented.
39.2.11 M Patient release criteria have been developed (i.e. when the patient can be released from the pulmonary function laboratory).

39.3 The reporting of exercise-induced bronchospasm testing results follows current ATS/ERS standards and best practices.

39.3.1 The reported results of exercise induced bronchospasm testing include:
39.3.1.1 M pre-exercise value.
39.3.1.2 M the lowest repeatable post-exercise value.
39.3.1.3 M the percent change.
39.3.1.4 FVC expressed in L (BTPS).
39.3.1.5 FEV1 expressed in L (BTPS).
39.3.1.6 PEFR expressed in L/s (BTPS).
39.3.1.7 raw recorded in cmH₂O/L/sec.
39.3.2 Variables that need to be recorded include:
39.3.2.1 the type of exercise device.
39.3.2.2 sustained work rate.
39.3.2.3 total exercise time.
39.3.2.4 maximum heart rate and length of time at target heart rate.
39.3.2.5 interpretation of the ECG.
39.3.2.6 oxygen saturation via pulse oximetry, if measured.
39.3.2.7 environmental factors including:
39.3.2.7.1 room temperature.
39.3.2.7.2 relative humidity.
39.3.2.7.3 barometric pressure.
39.3.2.8 additional provocations if applicable:
39.3.2.8.1 dry air.
39.3.2.8.2 cold air.
39.3.2.8.3 delivery method.
39.3.2.9 clinical signs and symptoms.
39.3.3 bronchodilators or other medications administered if applicable:
39.3.4.1 spirometry data from post-bronchodilator stage.
40.0 Conductance/resistance testing by body plethysmography is performed according to current ATS/ERS standards and best practices.

40.1 Equipment used for conductance/resistance testing by body plethysmograph follows current ATS/ERS standards and best practices.

- 40.1.1 Pressure, volume, or flow-type plethysmographs are used.
- 40.1.2.0 Transducers in the plethysmograph meet the following specifications:
  - 40.1.2.1 Mouth pressure: ± 20 to 50 cmH₂O.
  - 40.1.2.2 Box pressure: ± 2 cmH₂O (with a 500 L box).
  - 40.1.2.3 Flow: < 2 L/s.
  - 40.1.2.4 The pressure transducer tubing is connected in proper sequence according to manufacturer recommendation.
- 40.1.3 The door seal of the plethysmograph is checked to ensure it is leak free each day of use.
- 40.1.4 The mouth shutter closing speed and ease of activation, closure and release is checked.
- 40.1.5 Calibration of the volume, flow and pressure measuring components is performed at least once each day before testing patients and every 4 hours during use.
- 40.1.6.0 Volume measuring-device calibration is performed daily with a 3.0 L syringe.
- 40.1.6.1 The accuracy limit for recovered volume is ±3.5% of the syringe.
40.2  Conductance/resistance by body plethysmograph testing follows current ATS/ERS standards and best practices.

40.2.1.0  The patient is asked if they have complied with preparation criteria:
40.2.1.1.0  refrained from smoking for at least one hour prior to testing.
40.2.1.1.1  the time of the last cigarette smoked is recorded.
40.2.1.2  refrained from heavy exercise for one hour prior to testing.
40.2.1.3  refrained from eating a large meal at least one hour prior to testing.
40.2.1.4  supplemental oxygen and intravenous infusions are discontinued before entering the plethysmograph when possible.

40.2.2  Bronchodilators are avoided prior to testing if pre- and post-bronchodilator testing is to be performed.

40.2.3  The patient pants small and uniformly between 1.5 - 2.0 breaths per second.
40.2.4  Open shutter loops are closed or nearly closed and linear.
40.2.5  The entire tracing is visible and within the calibrated pressure range.
40.2.6  Once two to three acceptable open-shutter loops have been collected, close the mouth shutter and instruct the patient to continue panting.
40.2.7  The displayed Pao/Pbox loop is closed or nearly so.
40.2.8  Acceptable pressure changes are within the calibrated pressure range of each transducer.

40.2.9  The entire tracing is visible.
40.2.10  During closed-shutter loop data collection, the shutter is closed for only a brief period of time and generally at least 2 to 3 breaths should be collected.
40.2.11  The mouth shutter is opened and the patient is instructed to return to normal breathing.
40.2.12  If serial measurements are to be performed, the panting frequency is kept the same to aid in the interpretation.

40.3  The reporting of Conductance/Resistance by body plethysmograph testing results follows current ATS/ERS standards and best practices.

40.3.1.0  Each maneuver is visually inspected to ensure:
40.3.1.1  it meets acceptability criteria.
40.3.1.2  there was no evidence of thermal drift.
40.3.1.3  the panting frequencies were similar.
40.3.1.4  angles adjustments are reviewed and consistent.

40.3.2.0  The raw and related indices are calculated appropriately:
40.3.2.1  from the ratio of open- and closed shutter tangents for each maneuver.
40.3.2.2  are averaged from 3 - 5 separate, acceptable maneuvers.
40.3.2.3  have an open shutter tangent measured between +0.5 to -0.5 L/s.

40.3.3  Report of test results should contain a therapist’s statement about test quality, patients’ understanding of testing process, and, if appropriate, which criteria were not achieved.
41.0 Arterial blood gas analysis is performed according to current ATS/ERS standards and best practices.

41.1 Samples for blood gas analysis are collected and handled according to ATS/ERS standards and best practice.

41.1.1 [ ] Staff performing arterial punctures are aware of procedure dangers and precautions to minimize hazards to the patient.

41.1.2 [ ] There is a policy that defines the qualifications, training and competency assessment for staff collecting arterial punctures.

41.1.3 [ ] Appropriate collection material is available.

41.1.4 [M ] Patient identification is confirmed by the collector using a minimum of two identifiers prior to collection of the sample.

41.1.5.0 [ ] Acceptable identifiers are defined and listed and at a minimum include:

41.1.5.1 [ ] first and last name.

41.1.5.2 [ ] identification number.

41.1.6 [ ] The patient is examined for the presence of a radial artery occlusion prior to arterial puncture using a modified Allen’s test.

41.1.7 [M ] Routine precautions are used in the collection of blood.

41.1.8 [M ] Unaltered gloves are worn during phlebotomy.

41.1.9 [ ] Safety engineered needles are used during the arterial puncture.

41.1.10 [ ] Site selection for arterial puncture is appropriate.

41.1.11 [M ] The puncture site is properly cleaned.

41.1.12 [ ] Appropriate precautions are taken to prevent post-arterial puncture bleeding.

41.1.13 [ ] Special instructions are available for patients on blood thinners.

41.1.14 [ ] There is a process that addresses instances when arterial puncture is difficult.

41.1.15 [M ] Blood samples are labeled immediately after the collection process in the presence of the patient by staff collecting the sample.

41.1.16 [M ] Samples are labeled during the collection process in a manner that connects the patient to that sample (Intent: It may not always be possible to label a sample in the presence of the patient or other types of samples may be collected by non-laboratory staff).

41.1.17 [M ] The identity of the staff member collecting the sample is recorded.

41.1.18 [M ] The date and time the sample is collected is recorded in the information system or on the sample label.

41.1.19 [M ] Sample collection devices are disposed of in an appropriate and safe manner.

41.1.20 [ ] The sample is analyzed promptly (within 30 minutes) or precautions are taken to maintain the PaCO₂ and PaO₂ levels.
41.2 Appropriate QC and proficiency testing is performed for arterial blood gas analysis

41.2.0 Internal QC is performed for blood gas analysis including:
41.2.1 the mean and standard deviation for each constituent (pH, PCO₂, PO₂) is established for each new lot of QC material.
41.2.2 QC policies and procedures are documented and maintained.
41.2.3 QC results are reviewed and verified at regular intervals to detect trends and outliers.
41.2.4 when QC problems are identified, procedures are implemented to determine cause(s).
41.2.5 QC data is summarized monthly.
41.2.6 the medial leader establishes the acceptable range for QC.
41.2.7 QC material is analyzed every eight hours or on day of testing.
41.2.8 QC records are maintained for a minimum of two years.
41.2.9 QC material characteristics are similar to patient samples, where possible.
41.2.10 procedures are in place for the appropriate handling of patient samples while QC problems are investigated.
41.2.20 Proficiency testing (PT) is performed as appropriate:
41.2.21 the laboratory participates in the appropriate mandatory PT programs.
41.2.22 PT samples are handled in the same manner as patient samples.
41.2.23 PT results are regularly monitored by the medical leader or designate.
41.2.24 unacceptable results are investigated.
41.2.25 preferential conditions for PT are avoided.
41.2.30 If other analytes are reported out (e.g. ionized calcium, electrolytes) appropriate QC and PT is performed for those analytes.
41.2.31 A record of corrective action is maintained and filed with the Diagnostic Accreditation Program of B.C., if appropriate.

Internal QC is performed for hemoximetry/co-oximetry including:
41.2.4.1 The mean and standard deviation for each constituent (tHb, COHb, MetHb) is established for each new lot of QC material.
41.2.4.2 An adequate number of samples (e.g. 20) of each level of the new lot number is analyzed.
41.2.4.3 The values for each constituent at each level are statistically analyzed for mean and SD.
41.2.4.4 The acceptable range for each constituent is defined, ensuring it is consistent with the clinical needs for analytic inaccuracy.

Commonly used rules define when quality assurance actions should be taken when analyzing QC materials:
41.2.4.5.1 When one observation exceeds the mean ±2 SD, a “warning” condition exists and usually a repeat run is made.
41.2.4.5.2 When one observation exceeds the mean ±3 SD, an “out of control” condition exists.
41.2.4.5.3 When two consecutive observations exceed the mean ±2 SD, an “out of control” condition exists.
41.2.4.5.4 When four consecutive observations exceed the mean ±1 SD in the same direction, an “out of control” condition exists.
41.2.4.5.5 When 10 consecutive observations fall on the same side of the mean, an “out of control” condition exists.
41.2.4.5.6 M □ If an “out of control” condition exists, equipment troubleshooting should be performed and quality control verified to assure an “in control” condition exists prior to analysis of specimens.

41.2.4.5.7 □ Appropriate documentation of actions taken and results of verification are required.

41.2.4.5.8 M □ Duplicate sample analysis is performed on different instruments to verify acceptable inter-instrument variance.

41.3 Arterial blood gas analysis is performed according to CLSI standards and best practice

41.3.1.0 ☐ Calibration of the blood gas analyzer is performed as appropriate:

41.3.1.1 □ a one point calibration is performed every 30 minutes or prior to every sample.

41.3.1.2 □ a two point calibration is performed every 8 hours or on the day of testing.

41.3.1.3 □ calibration material is labeled with initial date of use and expiration date.

41.3.1.4 □ each new lot of calibration material is validated or verified prior to use.

41.3.2 □ The manufacturer’s step-by-step instructions or a detailed procedure are followed.

41.3.3 □ Blood samples are mixed thoroughly prior to analysis.

41.3.4 □ The internal temperature of the analyzer is checked and the data recorded.

41.3.5 □ Co-oximetry and hemoximetry samples are analyzed two or more times until two successive tHb results are within 0.2mg/dL.

41.4 Arterial blood gas analysis is reported according to CLSI standards and best practice.

41.4.1.0 ☐ Blood gas results are checked and repeated, or not reported if they are:

41.4.1.1 □ internally inconsistent (e.g. pH 7.40, pCO₂ 25 mmHg [3.3 kPa] and a reported bicarbonate of 24 mmol/L).

41.4.1.2 □ at the extremes of the range of expected values.

41.4.2.0 ☐ The complete report contains other relevant information:

41.4.2.1 □ collection date and time.

41.4.2.2 □ collection site.

41.4.2.3 □ the source of the sample (e.g. arterial, capillary).

41.4.2.4 □ the FIO₂ level.

41.4.2.5 □ ventilator settings.

41.4.2.6 □ comments regarding the quality of the sample.

41.4.2.7 □ delays in analyzing the sample.

Hemoximetry and co-oximetry is reported according to ATS/CLSI standards and best practice:

41.4.2.8 ☐ the sample is analyzed according to specific manufacturer’s recommendations.

41.4.2.9 □ there are procedures to address O₂Hb and COHb in the presence of HbF.

41.4.2.10 □ there are procedures to address MetHb values >10%.

41.4.2.11 □ a comment is included that addresses MetHb elevation due to the presence of Methb, SulHb or any of several medical dyes such as methylene blue.

41.4.2.12 □ if methylene blue is used to treat the high MetHb levels, report that all parameters are not valid and type in comment section: “Another method of analyzing MetHb should be used”.

41.4.2.13 □ There are processes to correct for interfering substances (e.g. HbF, bilirubin).
42.0 Reports are in a standardized format that provides necessary information for clinical decision making. (NB These criteria and descriptors apply to the specific reporting listed in 33.0 - 41.0).

42.1 Reports are comprehensive and include appropriate information.

- Reporting of results follows ATS/ERS standards.
- Reports are clear and legible.
- Reports identify the patient, requestor, report recipients and the laboratory performing the procedure, name of the exam/procedure/test, date.
- Every procedure requested is reported (with data or comments).
- Clearly understood predicted values are provided when appropriate.
- Therapist and/or physician comments are provided when appropriate.
- Final reports contain staff comments assessing patient effort and performance.
- Reports indicate data that does not comply with ATS/ERS criteria.
- Patient results are correlated before reporting.
- Multiple page reports include patient identifiers on each sequentially numbered page.
- Reports indicate when performance or technical difficulties are suspected to contribute to a compromised result.
- Reports indicate when a non-standardized or alternative method is used (e.g. patient breathing through a tracheostomy, patient standing during the test).
- The staff performing the procedure is recorded.
- Test results from other agencies or facilities are accurately recorded when necessary (e.g. blood gas).
- Previous reports are included with current results to enable comparison interpretation.
- Final reports with numeric and graphic results include:
  - patient first and last name.
  - second identifier.
  - height and weight.
  - name of facility performing test.
  - date and time.
  - therapist initials or name.
  - calibration date.
  - recommendations for follow-up including further procedures.
  - Reversibility criteria have been established and follow ATS/ERS standards.

42.2 There are policies and procedures in place to deal with corrected reports.

- Procedures or mechanisms are in place to detect and correct reporting errors.
- Corrected and addendum reports are clearly identified.
- Both the original result and the corrected result are reported.
- The date and time the change was made is noted.
- Notification of clinical staff is recorded.
- Corrected reports are reviewed by the medical leader or designate as appropriate.
- Corrected reports are investigated as necessary.
42.3 Reports and reporting processes meet the needs of test requestors.

42.3.1 Abnormal results are reported by rapid mechanisms.
42.3.2 Feedback from end users is considered when developing critical values, criteria and comments.
42.3.3 The pulmonary function laboratory shares responsibility with the requester for ensuring that reports are received by the appropriate individuals.
42.3.4 Reported results can be promptly retrieved.
42.3.5 When appropriate, an interim report of results is distributed.
42.3.6 Individualized narrative results contain the identification of the person interpreting the results.
42.3.7 Results are reported in an appropriate time frame.
42.3.8 Reports and tracings are reviewed for completeness, accuracy and timeliness.
42.3.9 The appropriate length of data and information storage is defined by the medical leader considering all relevant requirements.

42.4 There are policies and procedures in place to deal with critical results.

42.4.1 Critical results are established for procedures as appropriate.
42.4.2 Critical results are reported in real time to a real person.
42.4.3 Contingency plans are available in the event that the requesting physician cannot be contacted.
42.4.4 Actions taken in response to critical results are documented.
42.4.5 Criteria are established for the notification of a respirologist.
42.4.6 There is a mechanism to address significant discrepancies between emergency/preliminary reports and final reports.
42.4.7 Urgent, unexpected or unusual findings that require immediate patient management decisions are reported to the referring physician rapidly.

Pulse Oximetry

43.0 Pulse oximetry testing is conducted in a way that ensures meaningful, relevant data is reported.

43.1 Pulse oximeters are validated and used correctly to ensure the accuracy of test data.

43.1.1 M The pulse oximeter and related accessories have been validated by the manufacturer by a comparison of values and calibration curve.
43.1.2 M Pulse rate and oxygen saturation are sampled at least every six seconds. Guidance: Sampling time should be frequent enough to ensure that significant events are not missed.
43.1.3 The ability of the oximeter to quantitate the degree of hypoxemia has been assessed.
43.1.4 M Assessment of the agreement between the SpO₂ and the actual SaO₂ result is initially performed with intermittent reevaluation.
43.1.5 When disparity exists between SpO₂ and SaO₂ reading, or disparity exists between the SpO₂ and the clinical presentation of the patient, possible causes are explored before results are reported.
43.1.6 Measurements are correlated with the patient’s clinical condition when appropriate.
43.1.7 ☐ Monitoring at other sites or appropriate substitution of instruments or probes is used to reduce discrepancies.

43.1.8 ☐ Situations that may affect pulse oximetry results are defined (e.g. abnormal hemoglobins, intramuscular dyes, external sources of motion, ambient light, electrical interferences).

43.1.9 ☐ Oximeter types throughout the testing continuum are standardized. Intent: Since there are differences in accuracy among various oximeter brands and types, the same type of device should be used for serial measurements on a patient.

43.1.10 M ☐ The probe is cleaned between patient applications according to manufacturer recommendations.

43.1.11 M ☐ If the sensor is damaged in any way it is replaced.

43.2 Oximetry tests are set up in a manner that ensures accurate results.

43.2.1 M ☐ An appropriate probe (e.g. finger, ear, nose or forehead) is selected based on the clinical requirements of the patient.

Guidance: There are limitations for each type of probe. For example, finger probes are less accurate than forehead probes in cases of poor perfusion. Staff should be aware of the limitations of different devices.

43.2.2 M ☐ Nail polish and/or artificial acrylic nails are removed when finger probes are used.

43.2.3 ☐ Good blood flow is encouraged for a peripheral site probe. Guidance: Actual physical rubbing may be required to stimulate blood flow.

43.2.4 ☐ The instrument is allowed to search for and lock onto the pulsatile portion of the perfusion.

43.2.5 M ☐ The accuracy of capture is evaluated by comparing the palpated pulse to the reported heart rate on the device.

Overnight Oximetry

44.0 Overnight oximetry tests are conducted and reported in a manner that ensures accurate results.

44.1 The patient receives instruction on pulse oximeter use.

The patient receives instruction that includes:

44.1.1 M ☐ turning the oximeter on and off.

44.1.2 M ☐ placing and securing the probe.

44.1.3 M ☐ ensuring that a good signal is achieved.

44.1.4 M ☐ maintenance of a diary to record events that may affect test interpretation.

44.1.5 ☐ precautions to prevent motion artifact.

44.1.6 ☐ precautions to avoid exposure of the measuring probe to ambient light.

44.1.7 M ☐ New batteries are used for every overnight oximetry test. Guidance: In oximeters that have replaceable batteries (e.g. AA or 9V batteries), new batteries should be used for every patient. In oximeters that have a rechargeable power pack, steps to ensure that the power pack remains viable should be defined.

44.1.8 M ☐ The date and time settings of the oximeter are verified prior to testing.
44.2 Data from overnight oximetry is effectively incorporated into the report.

44.2.1 Pulse rate and oxygen saturation data are collected for at least four hours.

Guidance: Six hours of data is preferable.

This data includes:
- SpO₂% mean.
- SpO₂% minimum.
- Time the SpO₂ is below 88%, 85%, and 80%.
- Desaturation index (the number of 4% desaturations/hour).
- Rate, mean, minimum and maximum.
- Plot of SpO₂ and cardiac rate for the duration of the test.
- Interpretation of findings.
- Any pattern of clustering events or bursts of desaturation interspersed with more normal saturation.

When required, additional information is obtained that may facilitate improved interpretation of overnight oximetry studies including:
- Medical history and physical examination findings.
- Body mass index.
- Indication that Continuous Positive Airway Pressure (CPAP) was used in cases of CPAP therapy.
- Sleep history (including Epworth Sleepiness Scale or other sleep questionnaires).
- Spirometry.
- ECG and or LVEF.
- Confirmation from the patient that sleep actually took place in studies that are apparently normal or close to normal.

Exercise Testing for the Assessment of Desaturation

Exercise testing for the assessment of desaturation is also known as walking oximetry. Although the timing of the test often extends to six minutes and it may be performed in a corridor, it is different from a “Six Minute Walk Test”. See accreditation standards 37.1 - 37.3 for specific details on the Six Minute Walk Test.

45.0 Exercise testing for the assessment of desaturation is safe and conducted in a way that ensures meaningful, relevant data is reported to determine the oxygen requirements of patients.

45.1 Patient exclusion criteria for exercise testing for the assessment of desaturation have been established.

Patient resting parameters are recorded including:
- SpO₂.
- Heart rate.
- Blood pressure.
- Perceived dyspnea on the Borg and/or visual analog dyspnea scale.
- Arterial blood gases and/or co-oximetry are performed prior to testing.
- Pre-test oximetry is performed to assess the severity of hypoxemia and anticipate the oxygen level during testing.
- Exclusion criteria are defined.
Absolute contraindications for testing include:

- 45.1.8 M unstable angina.
- 45.1.9 M uncontrolled systemic hypertension.
- 45.1.10 M recent systemic or pulmonary embolism.

Relative contraindications for testing include:

- 45.1.11 resting diastolic blood pressure >110 mmHg or resting systolic blood pressure >200 mmHg.
- 45.1.12 unstable (fluctuating) pulse oximetry reading.
- 45.1.13 significant weakness, pain, fever, dyspnea, lack of coordination, or psychosis that renders the patient incapable of performing the test.
- 45.1.14 recent myocardial infarction. Guidance: Myocardial infarction (MI) within the previous 4 weeks is a relative contraindication. However, the test may be indicated in MI patients with coexisting lung disease to ascertain the need for supplemental O₂ during ambulation.
- 45.1.15 pH <7.30 or >7.50.
- 45.1.16 partial pressure of carbon dioxide in the arterial blood (PaCO₂) >50 mmHg with pH <7.30.
- 45.1.17 carboxyhemoglobin (COHb) >8%.
- 45.1.18 methemoglobin (METHb) >5%.
- 45.1.19 total hemoglobin (tHb) <80 g/L.

45.2 Criteria are established for the use of supplemental oxygen during exercise testing.

Oxygen titration is initiated when indicated:

- 45.2.1 partial pressure of oxygen in the arterial blood (PaO₂) <55 mmHg
- 45.2.2 saturation level of oxygen in hemoglobin (SaO₂) <87%
- 45.2.3 saturation level of oxygen in hemoglobin by oximetry (SpO₂) <88%
  Guidance: If these values are obtained while the patient is resting, and breathing room air, the exercise test should be performed with supplemental oxygen.

- 45.2.4 The approach to determine the lowest oxygen flow rate required is established.
  Guidance: Oxygen may be adjusted while the patient continues to exercise or exercise is stopped, the flow rate is adjusted and exercise is resumed after equilibration.

- 45.2.5 Oxygen saturation is measured during exercise.
  Guidance: Measuring oxygen saturation immediately after exercise is not appropriate. In hypoxemic patients, oxygen saturation generally increases rapidly after cessation of exercise.

- 45.2.6 Oxygen is increased in 0.5-1.0 L/min increments until the SpO₂ just exceeds 90%.
- 45.2.7 The patient is observed for SpO₂ stability.
- 45.2.8 The SpO₂, litre flow, mode of delivery and time on oxygen are recorded.

If supplemental oxygen is used, relevant details are recorded including:

- 45.2.9 flow rate.
- 45.2.10 delivery device.
- 45.2.11 details of how the tank was carried (e.g. by patient, by staff etc.).
45.3 Exercise testing for the assessment of desaturation is safe, standardized and ensures meaningful data is accumulated.

45.3.1 Exercise is performed on a treadmill.

**Intent:** Although exercise can be performed in a hall corridor, both treadmills and cycles provide a better monitoring environment. The major disadvantage of informal corridor walks is the lack of information about subtle physiologic changes during exercise, and information on the relationship of work rate to desaturation. Cycle ergometer testing does not mimic daily living conditions and with some patients it is difficult to reach a desaturation point, since they are not carrying their own body weight. In cases where it is difficult for a patient to reach desaturation, on a cycle ergometer (e.g. morbid obesity or interstitial lung disease, corridor or treadmill walking should be attempted).

For corridor testing:

45.3.2 the patient walks (without running) at a vigorous pace that they can maintain for 5-10 minutes.

45.3.3 a minimum of 30 metres of flat, unobstructed corridor is available to conduct the test.

For cycle ergometer testing:

45.3.4 handlebars and saddle heights are adjusted to the appropriate level.

45.3.5 instructions addressing the recommended cycling rate (RPM) are given.

45.3.6 the beginning workload is 40-80 RPM at 15-20 watts.

**Guidance:** This workload could be lower based on patient ability.

For treadmill testing:

45.3.7 treadmill-walking techniques are explained or demonstrated.

45.3.8 patients are advised not to talk during the exercise testing unless necessary to inform the therapist of adverse symptoms.

45.3.9 a brief trial walk is used to familiarize the patient with the equipment.

45.3.10 a spotter is positioned at the rear of the treadmill.

45.3.11 the treadmill speed and grade are determined by the therapist based on the activity level that elicits dyspnea in a given patient.

**Guidance:** Typically this is 1MPH, but it varies from patient to patient.

45.3.12 the patient rests a minimum of 5 minutes prior to starting the test.

45.3.13 the patient exercises 5-10 minutes.

45.3.14 M a minimum of three minutes of exercise is achieved.

45.3.15 the workload is increased or decreased as tolerated by the patient.

**Guidance:** Precautions should be taken to ensure the therapist supervising the testing does not set the pace. In order to do this the therapist should walk behind the patient as opposed to in front of or beside the patient. When walking behind the patient care must be taken to ensure the patient does not feel rushed during testing.

Exercise parameters are recorded during testing at 30 second intervals:

45.3.16 SpO₂

45.3.17 heart rate.

**Guidance:** Precautions should be taken to prevent error in recording these parameters. A stop-watch or other dedicated timer should be used and staff must be vigilant to recognize subtle changes during testing.
Exercise endpoints are defined including:

- completion of the predetermined exercise time.
- \( \text{SpO}_2 < 88\% \) (80\% in the case of home oxygen assessment).
- adverse symptoms (e.g. severe angina, tightness or wheezing; confusion, nausea or ataxia; tachycardia > 160 bpm).
- patient cannot continue with testing.

Exercise parameters are recorded including:

- total exercise time.
- end of exercise \( \text{SpO}_2 \).
- end of exercise heart rate.
- blood pressure.
- Borg Scale or visual analog scale results.
- any symptoms such as shortness of breath and/or leg fatigue.
- workload in watts (for ergometer cycle testing).

45.4 The reporting of exercise testing for the assessment of desaturation assists in the interpretation of patient’s oxygen requirements.

- The patient’s position and activity level is reported.
- If used, supplemental oxygen flow rate and delivery device is reported.
- The oximeter type, probe type and placement is reported.
- If performed, arterial blood gas results and directly measured saturations of \( \text{O}_2 \text{Hb} \), \( \text{COHb} \) and \( \text{MetHb} \) are reported.
- The stability and range of fluctuation of readings is reported as well as the length of observation of readings.
- The clinical appearance of the patient is included if significant, including peripheral perfusion, skin temperature, cyanosis and other signs and symptoms.
- Correlation of the heart rate readout on the oximeter with the actual palpated heart rate is reported.

Cardiopulmonary Exercise Testing

46.0 Cardiopulmonary exercise testing is safe and conducted in a way that ensures meaningful, relevant data is reported.

Cardiopulmonary exercise testing should be performed under the supervision of a physician appropriately trained to conduct clinical exercise tests and certified in advanced cardiac life support. The degree of supervision will be determined by the clinical condition of the patient being tested.

46.1 Patient exclusion criteria and criteria for discontinuing cardiopulmonary exercise testing have been established.

Patient resting parameters are recorded including:

- resting ECG.
- resting blood pressure.
- pre-exercise spirometry including maximum voluntary ventilation (MVV).
Resting Arterial Blood Gas results.

Guidance: See standards on arterial blood gas and co-oximetry testing 41.1 – 41.4

Pulse oximetry if indicated.

Guidance: See standards on pulse oximetry 44.1 - 44.2

Exclusion criteria are defined.

Absolute contraindications for testing include:

- recent complicated myocardial infarction.
- changes in the resting ECG that suggest an acute or recent myocardial event.
- unstable angina.
- uncontrolled cardiac arrhythmias.
- severe aortic stenosis and known or suspected dissecting aortic aneurysm.
- active or suspected acute pericarditis or myocarditis.
- acute congestive heart failure.
- acute febrile illness.
- acute asthma.
- recent systemic or pulmonary embolus.
- psychosis.

Relative contraindications for testing include:

- systemic hypertension with a resting systolic blood pressure >200mmHg or diastolic >120 mmHg.
- resting tachycardia (>120 beats per minute).
- frequent ventricular or atrial ectopy.
- moderate aortic stenosis.
- other moderate or severe valvular heart disease.
- known electrolyte abnormalities.
- uncontrolled diabetes.
- orthopedic limitations to exercise.
- neuromuscular, musculoskeletal or rheumatoid diseases that are exacerbated by exercise.
- advanced or complicated pregnancy.
- cardiomyopathy.

Criteria for stopping the exercise test (other than the patient’s fatigue and inability to continue) are defined:

- chest pain suggestive of ischemia.
- ischemic ECG changes.
- complex ectopy.
- second or third degree heart block.
- fall in systolic blood pressure >20 mmHg from the highest value during exercise.
- hypertension (>250 mmHg systolic; >120 mmHg diastolic).
- severe desaturation: $\text{SpO}_2 \leq 80\%$ when accompanied by symptoms and signs of severe hypoxemia.
- sudden pallor.
- loss of coordination.
- mental confusion.
- dizziness or faintness.
- signs of respiratory failure.
When exercise is terminated because of the above criteria, the patient is observed until stable and physiologic variables have returned to baseline conditions.  
See standards on handling medical emergencies 18.5.

46.2 Patients are monitored during Cardiopulmonary Exercise Testing.  
Routine measurement by electrocardiogram (ECG) are used during Cardiopulmonary Exercise Testing.

46.2.1 M Standard placement of ECG leads are used.
46.2.2 M Chest hair is removed when required.
46.2.3 M A clean razor is used and then discarded into an appropriate sharps container.
46.2.4 M The skin is cleansed and prepped as needed to eliminate artifact in the tracing.
46.2.5 M Limb leads are attached to both arms and legs.
46.2.6 M Precordial leads are attached to the correct anatomical positions.
46.2.7 M Cable stabilization is used to reduce motion artifact.
46.2.8 M There is a job aide that demonstrates the correct placement of Precordial leads.
46.2.9 M Changes on the ECG that require urgent medical attention are identified and advice is sought from the medical leader or other appropriate clinician.

Routine measurements of an exhaled gases are used during Cardiopulmonary Exercise Testing.

46.2.10 E Explain that the test is a maximum stress test, and that the mouthpiece or mask must be in place for the duration of the test.
46.2.11 M The mouthpiece is placed in the patient’s mouth and a nose clip is applied. Guidance: If a mask is used, ensure that it fits correctly and that no leaks are present.
46.2.12 M The patient is instructed to maintain a tight seal around the mouthpiece to reduce the incidence of an air leak.
46.2.13 M The patient is instructed to breathe quietly for 2 to 3 minutes. Feedback may be needed to avoid inappropriate breathing patterns (e.g. hyperventilation).
46.2.14 E End-points are explained to the patient (attainment of maximal heart rate, development of limiting symptoms, or blood pressure, ECG or O₂ saturation out of range) and the patient is reassured about safety.
46.2.15 E Exercise protocols designed to determine VO₂ max as one end point typically last about 10 minutes and the protocol is modified with this total expected exercise time in mind.

The patient is instructed about the use of symptom scales.

46.2.16 M The rate of perceived exertion (Borg scale).
46.2.17 M Other symptom scales (e.g. visual analog scale to score breathlessness); chest pain, chest tightness, asthma score, lightheadedness, leg fatigue.

46.3 The exercise methodology is safe and standardized.

For treadmill testing:

46.3.1 M the patient is instructed about the use of the treadmill.
46.3.2 M treadmill-walking techniques are explained or demonstrated.
46.3.3 M a brief trial walk is used to familiarize the patient with the equipment and check the ECG signal for motion artifact.
46.3.4 M a spotter is positioned at the rear of the treadmill.
46.3.5 The patient is instructed not to use their hands and arms for support during testing.

Guidance: If railings are used, the back of the hands or a light touch can be used for balance but the patient should avoid weight support which has an effect on VO$_2$max and exercise time. In addition, the use of upper extremities increases the muscle artifact in the ECG tracing.

46.3.6 Maximal incremental protocols are established.

Guidance: The treadmill protocol should be appropriate for the patient and clinical questions to be answered. Treadmill protocols may be based on the Bruce, Balke, and Naughton or other protocols.

46.3.7 Modification of treadmill protocols are performed to meet the exercise limitations of the patient.

46.3.8 Any modification of the treadmill protocol is documented.

For cycle ergometer testing:

46.3.9 The patient is instructed about the use of the cycle ergometer.

46.3.10 The handlebar and saddle height are adjusted appropriately.

46.3.11 When the pedal is at bottom center, knee flexion should be about 20°.

46.3.12 The patient is instructed on pedal speed (appropriate to ergometer) with a typical target of 60 rpm.

46.3.13 A brief trial with little or no power output is performed to familiarize the patient with the equipment and to check the ECG signal for motion artifact.

46.3.14 Maximal incremental protocols are established.

Guidance: The cycle ergometer protocol should be appropriate for the patient and clinical questions to be answered. Typically a ramp protocol is used for a cycle ergometer.

46.3.15 The protocol includes 3 minutes of unloaded pedaling.

46.3.16 The work rate is increased in 5 to 25 Watt increments every minute until the patient reaches volitional exhaustion, or test is terminated by the medical monitor.

46.3.17 The incremental exercise period is approximately 8-12 minutes in duration.

Guidance: With computer-controlled cycle ergometers, it is possible to increase the work rate continuously, usually every 1 to 2 seconds in a ramp-like fashion (ramp protocol). However, the total increment per minute should be 5 to 25 W/minute.

46.3.18 The work rate is decreased for patients suspected of having reduced exercise tolerance and the work rate is increased for very fit patients.

Cardiopulmonary exercise testing using an arm ergometer is used when appropriate including:

46.3.19 Patients with lower extremity impairment.

46.3.20 Occupational evaluation in patients whose work primarily involves upper body activity.

46.3.21 10- to 25-Watt increments in 2 minute intervals are recommended.

46.3.22 VO$_2$max for arm exercise is generally equal to about 70% of that for leg exercise.
46.4 Patient parameters are monitored and documented during Cardiopulmonary Exercise Testing.

46.4.1 ECG data is collected at 1 to 2 minute intervals during exercise and at the maximal work rate.

46.4.2 ECG data is monitored continuously for 10 minutes post exercise.

46.4.3 Blood pressure is measured every 1 to 2 minutes during exercise, at the maximal work rate, and during the recovery phase.

46.4.4 Subjective measurements (e.g., RPE) are measured at rest, during exercise and immediately post exercise.

46.4.5 At the termination of exercise the reason for stopping the test is defined and recorded (e.g., legs hurt, shortness of breath, or fatigue).

Intent: This may assist in the determination of maximal effort and help the clinician understand the patient’s exercise limitations.

46.4.6 Recovery includes a cool-down phase at a reduced work rate (e.g., unloaded pedaling) for 2 to 4 minutes followed by 2 to 6 minutes of rest with ECG and symptom monitoring.

46.4.7 Recovery values are stable before discontinuation of monitoring.

Intent: Recovery values do not have to reach pretest levels but should be stable.

46.5 The reporting of cardiopulmonary exercise testing results provides meaningful cardiac and pulmonary function data to clinicians.

Data is reported at a minimum from:

46.5.1 rest.

46.5.2 near or at the anaerobic threshold (AT) if identifiable.

Guidance: The conventional method for determining AT uses ventilatory equivalents plotted against VO$_2$. Usually, data are smoothed or averaged to reduce breath-by-breath variability, facilitating location of the AT. The AT coincides with the minimum of VE/VO$_2$. The VE/ VCO$_2$ should either be constant or declining in the region around the AT. An increasing VE/ VCO$_2$ suggests the increase in both parameters is due simply to hyperventilation rather than to a change caused by lactic acidosis. AT can also be located using V-slope analysis, where the VCO$_2$ (vertical axis) is plotted versus the VO$_2$ (horizontal axis). The AT is the point where the slope of VCO$_2$ versus VO$_2$ increases; this can be located either manually or by using computerized analytic routines. If computerized analysis routines are used, the AT should always be verified by visual inspection of the data.

46.5.3VO$_2$ max and V CO$_2$ are reported at STPD conditions in L/min.

Guidance: VO$_2$ max may also be normalized for body weight (mL/min/kg). However, this may be misleading in obese individuals.

46.5.4 V$_E$ is reported at BTPS conditions in L/min.

46.5.5 PaO$_2$, PaCO$_2$ (if obtained) and P$_{ET}$CO$_2$ are reported in mmHg.

46.5.6 SpO$_2$ and SaO$_2$ (from CO-oximetry) are reported as percent.

Variables are defined to detect maximal performance.

46.5.8 Heart rate is close to the maximal predicted: (210 - 0.65 x (age), (preferred), or 220 – age).

46.5.9 V$_{E, max}$: between 60% - 80% of ventilatory capacity (Ventilatory Capacity = MVV or FEV$_1$ X 35 to 40).

46.5.10 SpO$_2$ <80% (In cases of severe hypoxemia a patient may terminate exercise.)

46.5.11 Metabolic work: RER equal to or greater than 1.10 to 1.15; lactate equal to or greater than 7 mMol.