



THE
COLLEGE
OF
PHYSICIANS
AND
SURGEONS
OF
ONTARIO

INDEPENDENT HEALTH FACILITIES

Clinical Practice Parameters and Facility Standards



Pulmonary Function Studies – 4th Edition, June 2014

(Revised October 2018)

The College of Physicians and Surgeons of Ontario

Vision Statement

Quality Professionals, Healthy System, Public Trust

Our Mandate

Build and maintain an effective system of self-governance.

The profession, through and with the College, has a duty to serve and protect the public interest by regulating the practice of the profession and governing in accordance with the Regulated Health Professions Act.

Our Vision Defined

Quality Professionals, Healthy System, Public Trust.

Our new vision is the framework by which we organize ourselves.

It guides our thinking and actions into the future. It defines not only who we are, but what we stand for, the role we see for ourselves, our critical relationships, in what system we work, and the outcomes we seek.

Each component of our vision is defined below:

Quality Professionals – as a profession and as professionals, we recognize and acknowledge our role and responsibility in attaining at a personal, professional, and at a system-level, the best possible patient outcomes.

We are committed to developing and maintaining professional competencies, taking a leadership position on critical issues that impact the performance of the system, and actively partner to provide tools, resources, measurement, to ensure the optimal performance at all levels of the system.

Healthy System – the trust and confidence of the public and our effectiveness as professionals is influenced by the system within which we operate. Therefore, we, as caring professionals, are actively involved in the design and function of an effective system including:

- accessibility
- the interdependence of all involved
- measurements and outcomes
- continued sustainability

Public Trust – as individual doctors garner the trust of their patients, as a profession we must aim to have the trust of the public by:

- building positive relationships with individuals
- acting in the interests of patients and communities
- advocating for our patients and a quality system

Our Guiding Principles

Integrity, accountability, leadership and cooperation

The public, through legislation, has empowered the profession to regulate itself through the College.

Central to the practice of medicine is the physician-patient relationship and the support of healthy communities. As the physician has responsibility to the patient, the profession has the responsibility to serve the public through the health-care system.

To fulfill our vision of quality professionals, healthy system, public trust we will work to enhance the health of the public guided by professional competence and the following principles:

Integrity – in what we do and how we go about fulfilling our core mandate:

- Coherent alignment of goals, behaviours and outcomes;
- Steadfast adherence to a high ethical standard.

Accountability to the public and profession – we will achieve this through:

- An attitude of service;
- Accepting responsibility;
- Transparency of process;
- Dedicated to improvement.

Leadership – leading by proactively regulating our profession, managing risk and serving the public.

Cooperation – seeking out and working with our partners – other health-care institutions, associations and medical schools, etc. – to ensure collaborative commitment, focus and shared resources for the common good of the profession and public.

Independent Health Facilities

Clinical Practice Parameters and Facility Standards

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(revised October 2018)*

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Preface

The Independent Health Facilities Act (IHFA), proclaimed in April 1990, amended in 1996 and 1998, gives the College of Physicians and Surgeons of Ontario the primary responsibility for carrying out quality assessments in Independent Health Facilities. These facilities may provide some of the following insured services:

- in diagnostic facilities: radiology, ultrasound, magnetic resonance imaging, computed tomography, nuclear medicine, PET, pulmonary function, and sleep studies
- in treatment or surgical facilities: one or more of a variety of procedures in peripheral vascular disease, plastic surgery, obstetrics and gynaecology, dermatology, nephrology, ophthalmology, and their related anaesthetic services and perhaps other specialties.

The College of Physicians and Surgeons of Ontario has a legislative mandate under the Act to perform quality assessment and inspection functions. This responsibility, and others set out by agreement with the Ministry of Health and Long-Term Care, contribute to the College achieving its goals as stated in the College's Mission Statement. An important goal of the College is to promote activities which will improve the level of quality of care by the majority of physicians. The Independent Health Facilities program helps reach this goal by developing and implementing explicit clinical practice parameters and facility standards for the delivery of medical services in Ontario, assessing the quality of care provided to patients, and as a result, promotes continuous quality improvement.

Purpose of Clinical Practice Parameters

The Independent Health Facilities clinical practice parameters and facility standards are designed to assist physicians in their clinical decision-making by providing a framework for assessing and treating clinical conditions commonly cared for by a variety of specialities. The primary purpose of this document is to assist physicians in developing their own quality management program and act as a guide for assessing the quality of patient care provided in the facilities.

Note: The parameters and standards are not intended to either replace a physician's clinical judgement or to establish a protocol for all patients with a particular condition. It is understood that some patients will not fit the clinical conditions contemplated by certain parameters and that a particular parameter will rarely be the only appropriate approach to a patient's condition.

In developing these clinical practice parameters, the objective is to create a range of appropriate options for given clinical situations, based on the available research data and the best professional consensus. The product, therefore, should not be thought of as being “cast in stone”, but rather subject to individual, clinically significant patient differences.

Role of the College of Physicians and Surgeons

At the beginning of this process, the College adopted the role of a facilitator for the development of clinical practice parameters and facility standards. Representatives of national specialty societies and sections of the Ontario Medical Association, and individuals with acknowledged skill, experience and expertise formed specialty-specific Task Forces.

The Task Force members' initial work, distributed in March 1991, was sent to the following organizations for their review and comments:

- all relevant specialty physicians in Ontario, national specialty societies and specialty sections of the Ontario Medical Association
- Ontario Chapter of the College of Family Physicians of Canada
- Canadian Medical Association
- American Medical Association
- Canadian Council on Health Facilities Accreditation (now the Canadian Council on Health Services Accreditation)
- College of Nurses of Ontario

The Task Forces continue to adhere to the following principles:

- clinical practice parameters must be based on the appropriate mix of current, scientifically-reliable information from research literature, clinical experience and professional consensus.
- any parameter-setting exercise must be done exclusively from the quality perspective. That may well mean that some of the conclusions reached could add to medical care costs.
- parameters have to be flexible enough to allow for a range of appropriate options and need to take into account the variations in practice realities from urban to rural areas.
- parameters need to be developed by consensus and consultation with the profession at large.
- parameters should provide support and assistance to physicians without boxing them in with "cookbook formulas."
- parameters will need to be regularly updated based on appropriate research studies.
- parameters should reduce uncertainty for physicians and improve their clinical decision-making.
- information on practice parameters must be widely distributed to ensure that all physicians benefit from this knowledge.

Responsibilities of the College

Responsibilities of the College include:

- assessing the quality of care when requested by the Ministry. The College will maintain a roster of physicians, nurses, technologists and others to serve as inspectors and assessors as required.
- inspecting the illegal charging of facility fees by unlicensed facilities when requested by the Ministry.

- monitoring service results in facilities. The College’s information system will monitor individual and facility outcome performance. This is a unique feature of the legislation, which for the first time in North America, requires facility operators to establish and maintain a system to ensure the monitoring of the results of the service or services provided in a facility.
- providing education and assisting facilities so that they may continually improve the services they provide to patients. The College will work with and assist physicians in these facilities so that they can develop their own quality management programs based on the parameters and standards, monitor facility performance by conducting quality assessments, work with facilities to continually improve patient services, assist in resolving issues and conducting reassessments as necessary.

Updating this Document

These parameters and standards are subject to periodic review, and amendments may be issued from time to time. Notifications of such updates will be mailed automatically to all relevant Independent Health Facilities. A comprehensive review and update of the parameters and standards will be undertaken at intervals not greater than five years. The external review process will be repeated to validate the new parameters as they are developed.

Note: Facilities must remain up-to-date with all information contained in this document, including externally-sourced material, such as content from outside organizations, as well as information made available via hyperlinks. In addition, while the CPSO reviews and updates externally sourced materials and hyperlinks in this document at regular intervals, it is possible that links may become broken or invalid over time. If that occurs, facilities are encouraged to source the updated links on their own.

Independent Health Facilities: Clinical Practice Parameters and Facility Standards

Pulmonary Function Studies

Volume 1 Facility Standards

Chapter 1 Definition of Pulmonary Function Studies

1.1 Purpose of Pulmonary Function Laboratories

The purpose of a Pulmonary Function Laboratory (PFL) is to provide the referring physician with accurate measurements of the functioning of a patient's respiratory system in a manner that is safe for the patient and favourable to obtaining the optimum health of the patient.

These standards provide a framework for the structure and operation of a PFL to help realize these goals. This section presents standards relating to Quality Advisor and medical staff, the technologists, the record keeping function of the lab, and establishing a quality management program. The circumstances of medical practice vary widely across the Province of Ontario; this will influence the manner in which any PFL implements these standards.

1.2 Classes of Diagnostic Services

Diagnostic Services licensed under the Independent Health Facilities Act (IHFA) are those services for which the "technical fee" (cost of providing the service) has been removed from the Schedule of Benefits for Physicians' Services (SOB). These services are identified by a fee listed under the "h" column of the SOB. These "H" fees are translated into "F" (facility) fees for purposes of the IHFA.

Four classes of diagnostic services have been established by the Ministry of Health and Long-Term Care:

- Class A includes oximetry at rest, with exercise, and sleeping with or without added oxygen (J323, J332, J334).
- Class B includes lung volumes (J307, J311) single breath diffusing capacity (J310), airways resistance (J306), non-specific bronchial provocative testing (J333), and the measurement of maximum inspiratory and expiratory pressures (J340).
- Class C includes stage I exercise testing (referred in this document as "Cardiopulmonary Exercise Test", Chapter 15), with or without added airflow measurements and performance of ECGs (J315, E450, E451).
- A final class of tests (other fee codes) requires individual approval for billing purposes (J309, J318, J319, J320, J322, J328, J330). These services are currently provided by a variety of physicians, in addition to those certified in Respiratory Disease.

Note: The facility licence granted by the Ministry of Health and Long-Term Care specifies the Classes of Diagnostic Services for which the facility may bill the Ontario Health Insurance Plan. The granting of a Class B licence does not include a licence for Class A tests unless Class A tests are specified on the licence.

The term "Level" is used by Respiratory disease specialists and does not have any legislative basis under the Independent Health Facilities Act.

- Level I facilities perform tests in Class A only.
- Level II facilities perform tests in Class A and B.
- Level III facilities perform tests in Class A, B and C.

These parameters and standards are the initial phase of what will be an ongoing program of quality management in the practice of pulmonary function in independent health facilities. This document has been divided into Volumes for ease of review.

Chapter 2 Staffing a Facility

2.1 Overview

Under the Independent Health Facilities Act (IHFA), every Independent Health Facility licensed to perform pulmonary function tests must employ a designated Quality Advisor.

Where an Independent Health Facility chooses to appoint a Medical Director, the Medical Director may also function as the Quality Advisor.

Staff must maintain patient confidentiality at all times.

2.2 Quality Advisor

The Quality Advisor is a physician licensed to practise in Ontario.

The Quality Advisor has the training and experience necessary to understand the physiological basis of the tests performed in the facility, to determine the relevance of these test results to the patient's clinical problem, and to advise the facility licensee on the conduct of all the professional aspects of the facility.

As evidence of the requisite training and experience the Quality Advisor:

- holds a specialty qualification from the Royal College of Physicians and Surgeons of Canada or its equivalent, in Respiriology

or

- physician involved in conducting and interpreting exercise testing must be a Respirologist, and have a minimum exposure of 30 cases

or

- in lieu of the above, has a minimum of one year's experience in executing and interpreting pulmonary function testing, such tests to include those performed by the independent health facility of which the physician is Quality Advisor. In addition, the years' experience is gained under the supervision of a Quality Advisor holding the qualifications referred to in the above points.

2.3 Quality Advisor Responsibilities

The Quality Advisor (QA) must be a physician licensed to practice in Ontario by the College of Physicians and Surgeons of Ontario and meet the qualifications as outlined above.

The Quality Advisor must submit the *Notice of Appointment of Quality Advisor* and *Quality Advisor Acknowledgement* forms to the Director, IHF. These forms are available at <http://www.health.gov.on.ca/en/public/programs/ihf/forms.aspx>

2.3.1 Role of the Quality Advisor

The role of the Quality Advisor is an important one. Quality Advisors play a vital role in the overall operation of the IHF to ensure that the services provided to patients are being conducted appropriately and safely.

Each IHF licensee is responsible for operating the facility and providing services in accordance with the requirements of the IHFA. Pursuant to O. Reg. 57/92 under the *Independent Health Facilities Act* (see *Appendix I*), “every licensee is required to appoint a Quality Advisor to advise the licensee with respect to the quality and standards of services provided in the IHF. The Quality Advisor must be a health professional who ordinarily provides insured services in or in connection with the facility and whose training enables him or her to advise the licensee with respect to the quality and standards of services provided in the facility”.

Note: The term “health professional” as referenced in the IHFA, refers to a physician.

2.3.2 Responsibilities of the Quality Advisor

The Quality Advisor is responsible for advising the licensee with respect to the quality and standards of services provided. In order to fulfill this duty the Quality Advisor:

- Shall personally attend the facility at least twice each year, and may attend more frequently, where in the opinion of the Quality Advisor it is necessary based on the volume and types of services provided in the facility. The visits may be coordinated as part of the Quality Advisory Committee (QA Committee) meetings.
- Shall document all visits to the facility made in connection with the Quality Advisor’s role.
- Shall ensure that a qualified physician be available for consultation during the facility’s hours of operation.
- Shall seek advice from other health professionals where in the opinion of the Quality Advisor it is necessary to ensure that all aspects of the services provided in the facility are provided in accordance with generally accepted professional standards and provide such advice to the licensee.
- Shall chair the QA Committee. The QA Committee shall meet at least twice a year if the facility employs more than six full-time staff equivalents including the Quality Advisor; otherwise the QA Committee shall meet at least once a year. Regular agenda items should include: review of cases; policies and procedures; quality control matters on equipment; incidents, medical and technical issues.
- Shall ensure all QA Committee meetings are documented.
- Obtain copies of assessment reports from the licensee/owner/operator. If deficiencies were identified in the assessment, the Quality Advisor shall review same with the QA Committee and document such review. The Quality Advisor’s signature is required on any written plan submitted by the licensee to the College.

The Quality Advisor shall advise the licensee on the implementation of an ongoing Quality Management (QM) Program, which should include, but not be limited to, the following:

- Ensuring ongoing and preventive equipment maintenance.
- Follow-up of interesting cases.
- Follow-up of patient and/or medical and technical staff incidents.
- Continuing education for medical and technical staff.
- Ensuring certificates of registration, BCLS, etc. are current.
- Regular medical and technical staff performance appraisals.
- Patient and referring physician satisfaction surveys.

The Quality Advisor will advise the licensee, and document the provision of such advice, in connection with the following:

- **Health professional staff hiring decisions**, in order to ensure that potential candidates have the appropriate knowledge, skill and competency required to provide the types of services provided in the facility.
- **Continuing education** for all health professional staff members employed in the facility, as may be required by their respective regulatory Colleges or associations.
- **Appropriate certification** for all health professional staff members employed in the facility with the respective regulatory Colleges or associations.
- **Leadership**, as may be required to address and resolve any care-related disputes that may arise between patients and health professional staff.
- **Appropriate resources** for health professional staff members employed in the facility.
- **Formal performance appraisals** for all health professional staff.
- **Technology** used in the facility, in order to ensure it meets the current standard(s) and is maintained through a service program to deliver optimal performance.
- **Establishment and/or updating of medical policies and procedures** for the facility, e.g., consultation requests, performance protocols, infection control, and standardized reports, and other issues as may be appropriate.
- **Equipment and other purchases** as may be related to patient care.
- **Issues or concerns** identified by any staff member, if related to conditions within the facility that may affect the quality of any aspect of patient care.
- **Establishing and/or updating system(s)** for monitoring the results of the service(s) provided in the facility.

If the Quality Advisor has reasonable grounds to believe the licensee is not complying with the licensee's obligation to ensure that services are being provided in accordance with the generally accepted

standards and to ensure that the persons who provide services in the facility are qualified to provide those services, the Quality Advisor **must** inform the Director of Independent Health Facilities forthwith in accordance with the provisions and Regulations under the IHFA.

2.4 Medical Staff

Medical staff includes other physicians employed by the facility who are licensed to practise in Ontario.

2.4.1 Medical Staff Qualifications

Such physicians:

- hold a specialty qualification from the Royal College of Physicians and Surgeons of Canada (or equivalent) in Respiriology

or

- hold another specialty qualification from the Royal College of Physicians and Surgeons of Canada (or equivalent) and have a documented minimum of three months prior training and experience on the respiratory disease service of a university-affiliated teaching hospital, such training includes experience in the execution and interpretation of pulmonary function tests

or

- in lieu of the above, have a documented minimum of six months prior clinical experience in the execution and interpretation of pulmonary function testing. Documentation must be available in the Independent Health Facility.

2.4.2 Medical Staff Responsibilities

The medical staff is responsible for:

- the safe, accurate, and reliable performance of those tests which the physician will be interpreting.
- promptly communicating test results to the referring physician.
- assisting the Quality Advisor in performing other responsibilities that may be assigned to the physician and for which the physician has had appropriate training.
- preparing written reports for the Quality Advisor detailing any concerns the physician may have as to the safe and proper conduct of the facility.
 - a copy of any such report is provided to the facility licensee.

2.5 Technologists

Technical staff includes registered cardiopulmonary technologists (RCPT(P)), registered respiratory therapists (RRT), or other health care professionals as defined in this chapter.

2.5.1 Technologist Qualifications

These facility standards categorize pulmonary function facilities into Levels I, II, III as defined in the Preface.

2.5.2 Level I Facility

At a Level I facility the technologist staff include but are not limited to:

- a registered cardiopulmonary technologist (RCPT(P))

or

- a registered respiratory therapist (RRT)

or

- a health care professional whose formal training included studies in the anatomy and physiology of the cardiorespiratory system and whose subsequent experience included one month of training in the performance and quality control of spirometry and flow volume loop testing.

Note: All technologists in a Level I facility have current certification in Basic Cardiac Life Support.

2.5.3 Levels II and III Facilities

At a Level II and III facility the technologist staff includes but are not limited to:

- a registered cardiopulmonary technologist (RCPT(P))

or

- a registered respiratory therapist (RRT). To work in a facility not staffed by RCPT(P), the RRT must have one month formal training performing the pulmonary function tests which are conducted in the Independent Health Facility.
- a health care professional whose formal training included studies in anatomy and physiology of the cardiorespiratory system and whose subsequent experience and demonstrated competence in the performance of the pulmonary function tests conducted. Training is completed under the direct supervision of an RCPT(P) or an RRT.

Note: All technologists in a Level II or III facility must have current certification in Basic Cardiac Life Support (BCLS).

2.5.4 Chief Technologist Qualifications

The designation of a Chief Technologist is recommended in a facility with more than three technologists.

When a Chief Technologist is designated, he or she is a:

- registered cardiopulmonary technologist (RCPT(P)) with 4 years facility experience in a Level II or III facility.

or

- registered respiratory therapist (RRT) with 4 years of facility experience in a Level II or III facility.

2.5.5 Technologist Responsibilities

Technologists are current with the changing technical trends in the cardiopulmonary field by attending conferences, meetings or other forms of continuing education, and reading current relevant literature.

Technologists are responsible for the day-to-day operation of the facility, including but not limited to:

- arranging patient appointments and staff work schedules.
- distributing to referring physicians and agencies the test requisitions and the completed test reports.
- maintaining proper policies and procedures.
- maintaining records of equipment calibration, maintenance, and repair procedures.
- maintaining copies of test observations and reports.
- maintaining administrative records.
- ensuring that safety policies and the equipment and facilities necessary for their implementation are in place and in working order.
- ensuring the safe and reliable performance of tests.
- observing infection control measures.
- maintaining all necessary facility supplies.

Technologists are also responsible for:

- performing testing procedures.
- implementing policies and procedures.
- assisting the Quality Advisor.

Chapter 3 Policies and Procedures

3.1 Overview

To ensure safe and reliable pulmonary function testing procedures among facilities, written policies and procedures are essential for a uniform response to emergencies, standardization of testing, and quality assurance.

The most current CPSO Practice Parameters should be used as the standard for test protocols.

The policies and procedures manual is reviewed annually, revised as necessary, and dated to indicate date of last time of renewal or revision. All staff must (acknowledge) document annual review/revision of the policies and procedures manual.

3.2 Policies and Procedures

Written policies and procedures are available for, but not limited to, the following:

3.2.1 Facility

- Overview of the lab
- Scope and limitation of services
- Map location of the lab
- Floor plan
- Organizational structure
- General office policies and procedures
- Patient Booking System and clinic patient flow
- New patient process including accepted referral sources; procedure to triage/ process referrals and book appointments; standard procedure for consultations, office visits, diagnostic and treatment services
- Policies and standard procedures for follow-up of established patients

3.2.2 Facility Staff

- Job Descriptions including BCLS & CME activities
- Delegated acts
- Training of new staff hires

3.2.3 Facility Contacts

- Staff
- Building hydro and security

- Emergencies – Fire, Police, Hospitals
- Vendors

3.2.4 Records and Communication/ Reporting & Privacy Principles

- Policies and procedure for record structure, maintenance, storage & destruction
- Confidentiality Policies
- Consent and Privacy Policies and Procedures

Note: PHIPA - The independent health facility is expected to implement the various privacy procedures and policies to maintain patient information confidentiality within the organization. The organization must respect all laws that apply to it, including laws relating to privacy, confidentiality, and security of records and access to records, including the Personal Health Information Protection Act, 2004.

Information and Privacy Commissioner/Ontario

Suite 1400 Bloor Street East

Toronto, ON M4W 1A8

www.ipc.on.ca

- Reporting Policies and Procedures
- Report/ chart procedures and standards
- Standard forms including (but not limited to):
 - requisitions
 - flow sheets
 - handouts and prescriptions
 - logs
 - incident/ accident/ complaint forms

3.2.5 Quality Management

- see Chapter 5

3.2.6 Equipment Maintenance

- Equipment list
- Routine maintenance, validation and calibration of equipment (logs to be maintained separately for these procedures)

3.2.7 Infection Control and Procedures

Basic supplies for infection, prevention and control are on site and used appropriately as per current provincial guidelines/policies. Resources are available through the **Provincial Infectious Diseases**

Note: Facilities should visit the website at least annually, during the review of their policies and procedures manual, to obtain the most recent updates.

3.2.8 Emergency Procedures and Safety Policies

The following list includes the minimum required policies and procedures:

- Fire and evacuation plan
- General safety and prevention of adverse effects including administration of supplemental gases
- Specific first aid measures and emergency procedures
 - cardiac arrest/ respiratory arrest
 - chest pain
 - shortness of breath
 - seizures
 - acute non chest pain
 - other medical emergencies
 - infection control (*see Infection Prevention and Control for Clinical Office Practice*).
 - other adverse health effects or non-medical emergencies
 - how to arrange for transfer of patient to a hospital
- Safety equipment list and medication control
- Policies for staff and patient security
 - general security policies and procedures
 - inappropriate patient behaviour
 - sexual harassment of patients and of staff
- Current Workplace Hazardous Materials Information System (WHMIS) and Material Safety Data Sheets (MSDS) – may be kept in a separate manual/ file

3.2.9 Incident / Complaint Procedures

- General policies on dealing with and documenting incidents and complaints including follow up.

3.2.10 Patients/Staff At Risk for Latex Anaphylaxis

Latex-free equipment and supplies must be used. Routine practices dictate that all staff wear gloves when in direct contact with patients.

Contact dermatitis (allergic or irritant) is a common consequence of using latex gloves, and this may be involved in the development of true allergies to latex. Immediate reactions might include:

- rhinitis
- conjunctivitis
- urticaria
- angioedema
- asthma
- anaphylaxis

Allergenic latex proteins are also absorbed on glove powder, and may become airborne and inhaled when gloves is removed. All staff is encouraged to review up-to-date Guidelines for the Management of Latex Allergies. Web-site address <http://acaai.org/public/physicians/latex.htm>

Chapter 4 Requesting and Reporting Mechanisms

4.1 Overview

Facility records are retained and maintained by the facility. Requisition and Reporting forms are used to record the following information:

- basic demographic information
- clinical information
- tests required
- other fee codes authorized.

4.2 Requisition Form

Written requisitions are completed for all pulmonary function tests performed in the facility.

When an order for a test(s) has been dictated by telephone, the person to whom the order was dictated transcribes the test(s) ordered, the working diagnosis, the name of the requisitioning physician, the date and time of the order and signs the record of the order.

The requisition, prepared by the facility and provided to referring agencies, conforms to the requirements described. ***Requisition and Reporting Forms (see Appendix III).***

4.3 Pulmonary Function Requisition

Basic demographic information is included on the Pulmonary Function Studies Requisition. Reserve an area at the upper right hand corner of the form for the Health Number imprint. The form is dated appropriately.

The information collected includes the patient's family name, first name and initial, date of birth, gender, full address and phone number. Unless a latex-safe environment has been provided, questions regarding latex allergy should be asked of all patients. Clinical information such as the presence of dyspnea, cough, or wheeze, is included in the requisition, as well as a list of the relevant medications that the patient is taking. Details of the patient's smoking history are also useful.

A working diagnosis and area for further comments is also present. The reason for testing is outlined on the requisition.

Note: Tests required may include spirometry or flow volume loop, even though they are not covered by the Independent Health Facilities Act. A post-bronchodilator test is performed when indicated.

These tests may act in a screening function and prevent redundant testing. For example, FEV₁ increases by 12% and 200ml or more after a patient uses a bronchodilator may be suggestive of airway reactivity.

The list of tests offered by the Independent Health Facilities as authorized should be available.

The requisitioning physician's signature and contact information including their OHIP billing number complete the form.

4.4 Test Results

The facility retains the original results of all measurements made for each test for a period of time as specified by the IHFA Regulations. *See Appendix I Independent Health Facilities Act - Ontario Regulation 57/92.*

4.5 Test Report

A report is provided to the referring physician for each test performed in the facility within 5 business days. Copies of all reports are retained with the requisition and original data for a period of time as specified by the IHFA Regulations.

The report includes the following information:

- personal data sufficient to identify the patient, the patient's age, height and weight (height in centimetres, weight in kgs); the referring and reporting physicians, the name of facility performing the test, and the test date.
- source of reference values used and whether racial correction is applied must be documented.
- initials of the person performing the test.
- comments as to the reliability of the patient's performance during the test, where necessary.
- a summary of the original data with associated graphs and calculations made during the test.
- If previous testing was performed, comments concerning changes or absence of change must be provided.
- the reporting physician's interpretation of the original data as well as, where appropriate, comments as to the relevance of the results to the patient's presenting problem or suggestions as to patient management arising from the results.

4.6 Report Form

The report form contains the same demographic information as the requisition and is dated appropriately. Where applicable, the lower limit of normal and percent predicted should be included in the report. The results can be expressed in a variety of ways (e.g., numerically or graphically), but should express readily the results of the test. Normal ranges for the results, appropriate to the tested individual, are included. The interpreter's signature completes the report.

Requisitions and report forms (preferably the originals) should be kept at the facility and should be available for inspection. Following a telephone requisition, the requisition must be signed by the requisitioning physician.

A written requisition from the referring physician is required by all facilities as stipulated in the Regulations under the Independent Health Facilities Act.

Chapter 5 Quality Management Program

5.1 Overview

Each IHF has a Quality Management Program supervised by the Quality Advisory Committee (QAC) as set out in the IHFA Regulations (see Appendix I).

The requirements for, and responsibilities of the Quality Advisor (QA) are detailed in Chapter 2 Staffing a Facility.

In addition to the Quality Advisor, the Quality Advisory Committee is comprised of other health professionals who provide health services in or in connection with the IHF.

The QA committee shall meet at least twice a year if the facility employs more than six full-time staff equivalents including the Quality Advisor, otherwise the QAC shall meet at least once a year. Regular agenda items should include: review of cases, policies and procedures; QC matters on equipment; incidents; staffing issues.

All QA Committee meetings shall be documented.

The Committee is to supervise creation and maintenance of a quality management program adequate to reach the goals detailed below.

The goals, procedures and protocols for the quality management program of the facility are written and included in the policy and procedure manual.

5.2 Goals of a Quality Management Program

The goals of a Quality Management program include but are not limited to, ensuring that :

- Studies conducted in the facility are safe
- Studies conducted are appropriate to deal with the problem(s) being investigated. .
- There is a system to deal with incomplete or inappropriate requests for services.
- Testing is performed correctly and consistently, and in accordance with currently published standards and methods. Studies are interpreted correctly, with clear and prompt reports to referring physicians.
- Study reports contain clear suggestions for management including reference to the problems or questions raised in the requisition.
- All staff at the facility maintain up-to-date knowledge of pulmonary function testing appropriate to their role at the facility.

5.3 Components of a Quality Management Program

- To ensure that the goals of the quality management program are met the Committee's tasks include but are not limited to: Review quality management goals and objectives annually.
- Supervise and document a systematic ongoing review of the facility policy and procedure manual.
- Review the Workplace Hazardous Materials Information System (WHMIS)/ Material Safety Data Sheets (MSDS) data on anything introduced to the facility since the last meeting to ensure appropriate policy and procedures are in place.
- Review the safety data on any equipment new to the facility since the last meeting, and ensure that all equipment in the facility meets safety standards.
- Review any incident or accident report since the last meeting and document any actions to prevent similar incidents or accidents. Provide a report of all such proceedings to the facility's Quality Advisor.
- Ensure there is a program to calibrate and validation data on testing equipment and to review any corrective actions that were required, and the outcome of those actions.
- Review the types of procedures conducted at the facility each year for anomalous or unusual patterns. Regularly reviewing calibration and validation data on testing equipment, noting any deviations from accepted norms and recording corrective action taken.
- Supervise and document an annual review of a random selection of at least 1% of patient records, or 10 records, whichever is greater, to ensure that any tests conducted were appropriate to the problems presented by the patient. The quality advisor shall document that they discussed the results of this review with the physician(s) working at the facility and that any appropriate action and follow-up has been undertaken.
- Supervise and document a program of annual performance reviews for all staff who have patient contact, including documentation of action taken to correct any significant deficiencies in performance.
- Ensure registration certificates, BCLS certificates, etc. are current
- Review the CME activities of the technical and medical staff
- Supervise discussion of interesting/challenging cases seen at the facility, and disseminate any teaching points to the staff.
- Regularly review any training or education program at the facility
- Document corrective actions for anomalies identified in any of the reliability checks detailed above, and document further checks that show effectiveness of the corrective action.

- Review results of regular surveys of patient, physician and staff satisfaction, documenting actions to address any suggestions, problems or issues raised (see Appendix IV and V)
- Monitoring the Program
- To monitor the program the Quality Advisory Committee shall be comprised of a minimum of 2 health professionals who provide health services in or in connection with the IHF, including at least one physician and at least one technologist.

The Quality Advisory Committee shall meet at least semi-annually, with minutes of the meetings. Quorum for meetings shall be 2, or 50% of the committee, whichever is greater. Members who cannot attend are to review, and sign off on, the minutes of that meeting

Recommendations from the Quality Advisory Committee shall be circulated to all staff as minutes of the meeting once they are finalized. These recommendations shall be reviewed at a General Staff meeting including all health professionals who provide health services in or in connection with the IHF. Such meetings shall be held at least semi-annually. Quorum for such meetings shall be 2, or 50% of the staff, whichever is greater. Staff members who cannot attend are to review, and sign off on, the minutes of that meeting.

Records of:

- Minutes of the Quality Advisory Committee.
- Minutes of general staff meetings
- Performance of the components listed above shall be maintained on file at the IHF in a form that is clear and easily accessible to a reviewer.

Chapter 6 Facilities, Equipment and Supplies

6.1 Overview

Facility standards are provided for the health and safety of both the facility staff and all patients. These include reference values, equipment (including gases and ventilation, electrical safety), infection control, and emergency procedures.

6.2 Facility Standards

Significant differences in test results often occur between and even within facilities due to the use of different techniques, measurements, calculations, predicted equations, and quality control. To reduce this variability, standards are published and/or generally accepted guidelines are established for all routine pulmonary function tests.

In this document, standards are presented for:

- **Oxygen Saturation by Pulse Oximetry**
- **6-Minute Walk Test (6MWT)**
- **Carbon Monoxide Diffusing Capacity**
- **Functional Residual Capacity by body plethysmography, closed circuit helium dilution and nitrogen washout**
- **Airway Resistance by body plethysmography**
- **Methacholine Challenge Test (Non-specific bronchial provocative test)**
- **Exercise-induced Bronchoconstriction Test**
- **Cardiopulmonary Exercise Test (Stage 1)**
- **Maximal Inspiratory Pressure and Maximal Expiratory Pressure**
- **Arterial Blood Sampling, Blood Gas Analysis and Hemoximetry**

References are provided for more detail on instrumentation, techniques, measurements, calculations, and quality control.

Note: Facility and technical standards must be included in the policy and procedures manual of the independent health facility. Standards and policies are updated at least annually and approved by the medical and technical directors of the pulmonary function facility.

The operating efficiency of any facility depends not only on the expertise of the staff but also on the reliability of the equipment which is used for testing.

Equipment selection is integral to acquiring accurate test results. This applies to all diagnostic equipment whether it is used for clinical, diagnostic, or epidemiologic purposes.

Instrumentation recommendations are followed to provide accurate data and information that is comparable from facility to facility and from one time period to another.

6.3 Equipment

Equipment accuracy is determined by regular calibration checks. The results obtained must conform to recognized standards. The frequency of calibration is mandated by documents of the ATS (American Thoracic Society) and ERS (European Respiratory Society) standards for spirometry, lung diffusion and lung volumes. Physicians and staff must be fully familiar with the most current recommendations of the ATS/ERS regarding pulmonary function standards.

Each facility must establish a Quality Control Program to monitor that the equipment used produces measurements within acceptable limits of accuracy and precision of a test procedure.

Compliance with the minimal recommendations for spirometry, lung diffusion and lung volumes as published in 2005 by the joint publications of the ATS/ERS Task Force is mandatory (Miller, MR, et al. 2005. ATS/ERS Task Force: General considerations for lung function testing. *Eur Respir J.* 26(1):153-61).

The following summarizes the standard equipment recommended by the ATS/ERS in its publications on spirometry, lung diffusion and lung volumes.

6.3.1 Spirometer

The accuracy of a spirometer system depends on the resolution (i.e., the minimal detectable volume or flow) and linearity of the entire system, from volume or flow transducer to recorder, display, or processor. An error at any step in the process affects the accuracy of the results obtained. The spirometer must be capable of accumulating volume for at least 15 seconds and measuring volumes of at least 8L (BTPS) for measurements of FVC and FEV₁. The spirometer must be capable of accumulating volume for at least 30 seconds for measurements of VC and IC.

Volume Accuracy

The accuracy of a spirometer measuring volume should be at least $\pm 3\%$ of reading or ± 0.05 L, whichever is greater, with flows between 0 and 14 L/s.

Time Calibration

The time scale of a mechanical recorder must be checked with a stopwatch. The indicated time must be accurate to within $\pm 2\%$.

Flow Resistance

The total resistance to airflow must be < 1.5 cm H₂O/L at 14.0 L/s

Flow Accuracy

In the range of flows to be measured (-14 to +14 L/s) the measured flows must be within $\pm 5\%$ of reading or ± 0.02 L/s, whichever is greater.

Whenever a flow signal is integrated to measure volume, the volume accuracy requirements are $\pm 3.0\%$ of reading or ± 0.05 L, whichever is greater, with flows between -14 to + 14L/s.

6.4 Quality Control

The equipment calibration and quality control must include the following:

- Records of acceptable operation of new equipment or equipment after repairs or other alterations
- Records of calibration and quality control logs
- Records of updates or changes in computer software, hardware and pulmonary function equipment operating system

Part of the quality control activities is data collection and analysis. All calibration and quality control data should be properly analyzed and plotted. The technologist must be familiar with the terms and definitions used in the quality control program. The following “Terms and Definitions” are obtained from Chapter 5 (pg. 1-2), “Quality Control of the Pulmonary Function Laboratory Management Manual, 2nd Edition by ATS, 2005.

- Terms and Definitions
- Accuracy
 - How well the measurement reflects the true or correct value.
- Precision
 - Measurement variability (repeatability); it is completely independent of accuracy or truth.
- Random errors
 - Errors that occur without prediction or regularity tend to decrease precision and often result from inherent variation in the instrumentation.
- Systemic error
 - Errors within the test system or methodology (e.g., instrument calibration or malfunction) that tend to produce bias.
- Biologic Standard
 - Healthy non-smoking individual used in quality control
- Standard deviation (SD)
 - A measurement of variability or tendency of values to vary from the arithmetic mean. It is the square root of the variance.
- Coefficient of variation
 - A mathematical expression of variability calculated by dividing the SD by the mean.

The following devices are required in calibration and quality control activities:

Calibrated Syringe

The accuracy of the calibrated syringe must be within ± 15 ml for a 3-L syringe or $\pm 0.5\%$ of the full scale. The calibrated syringe should be checked/revalidated at an interval (e.g., annually) recommended by the manufacturer. A leak check for the calibrating syringe should be performed monthly.

A computerized syringe (i.e., computerized forced vital capacity simulator) can be used for calibration and quality control of volume and flow parameters (FVC, FEV₁, FEF_{25-75%}, FEF_{25%/50%/75%}) measured by spirometers. Also, the computerized syringe checks the time scale accuracy indirectly. This calibration/quality control tool is ideal for assessing the accuracy of computerized spirometry systems (both hardware and software)."

Ambient Environmental Devices (Thermometer, Hydrometer and Barometer)

Internal temperature, humidity (if applicable) and barometric pressure devices, that form part of the pulmonary function system must be verified with an external traceable thermometer, hydrometer and barometer before equipment calibration or quality control.

In recent years, most spirometers in new pulmonary function systems are flow based because of their compact size. The volume based spirometer is less popular because of its inherent size. There are distinctive quality control procedures between volume-type and flow-type spirometers.

For Volume-type Spirometer:

The volume accuracy must be checked at least daily with a single discharge of a 3-L calibrated syringe. The measured volume should meet the accuracy requirement of $\pm 3.5\%$. (includes $\pm 0.5\%$ accuracy limit for 3-L syringe).

Leaks should be checked daily by applying a constant positive pressure of ≥ 3.0 cm H₂O with the tubing outlet of the spirometer occluded. A loss of > 30 ml after one minute indicates the presence of leakage. Corrective action must be taken before patient testing.

Linearity of the spirometer from zero to maximum volume should be checked at least quarterly by introducing 1-L increments from zero to maximum volume with a calibrated syringe. The linearity check is acceptable when the measured values meet the volume accuracy requirements of $\pm 3.5\%$.

For Flow-Type Spirometer:

The volume accuracy must be checked at least daily using a 3-L calibrated syringe to simulate inspiratory and expiratory flows at least three times to give a range of flows varying between ± 0.5 and ± 12 L/s with injection times of between 0.5 second and 6 seconds. The volume at each flow should meet the accuracy requirement of $\pm 3.5\%$.

Linearity of the flow sensor should be checked weekly using a 3-L calibrated syringe with three relatively constant flows, one at low flow (0-2 L/s), one at mid-flow (4-6 L/s) and one at high-flow (8-12 L/s). The linearity check is acceptable when the measured values meet the accuracy requirement of $\pm 3.5\%$ and difference between the highest volume and lowest volume is < 0.105 L.

The Facility must keep organized, easy to read binders for the following:

- Records of acceptable operation (verification and validation) of new equipment and servicing of equipment after repairs or other alterations
- Records of calibration and quality control logs

- Records of calibration of calibrators
- Records of preventive maintenance on daily, weekly or yearly basis as per manufacture recommendations
- Records of updates or changes in computer software, hardware and pulmonary function equipment operating system

All records should be kept for at least 2 years.

6.4.1 Gas Analyzers

Helium (He)/Methane (CH₄)/Neon (Ne) and carbon monoxide (CO) analyzers of a diffusion system.

As only the ratios of CO and He/CH₄/Ne are important, it is not necessary to accurately measure either CO or He/CH₄/Ne concentrations if the analyzers are linear. Though infrared devices for measuring CO concentrations are inherently non-linear, many of the instruments currently being marketed have circuitry to linearize them.

Computerized systems take the raw alinear output from the gas analyzer and apply a linearizing algorithm. It is assumed by the manufacturer that since the gas analyzer output will maintain its' non-linear characteristics and the analog-to-digital input card and the computer algorithm will never change, then the gas analyzers never need to be individually calibrated. The best check for valid test results is performing biologic calibrations on a number of individuals monthly.

Accuracy and Linearity

The meter or its linearized output is linear within $\pm 0.5\%$ of the full scale range.

For systems that do not have a linearizing algorithm known concentrations of gravimetrically analyzed gases are used to establish linearity in the helium analyzer which is linear by design.

The CO analyzer is calibrated using a dilution technique whereby a 0.3% gravimetric gas is diluted using a super syringe. The subsequent dilution of the helium is used to calibrate the expected (or true) dilution of the carbon monoxide.

All values plotted are within $\pm 0.5\%$ of the true concentration, (e.g., the acceptable accuracy range for 10% He is between 9.95 – 10.05%).

6.4.2 Gases and Ventilation

In facilities where oxygen, compressed air and a vacuum source are not provided in wall outlets, these must be available in the facility for regular use. Compressed gas cylinders must be properly labelled and secured to a wall or placed in a stationary cart whether or not they are in use.

In rooms where pharmacological challenge testing is done, adequate ventilation is available and filters are used on the expiratory circuit of the mouthpiece apparatus.

In addition, the Workplace Hazardous Materials Information System (WHMIS) is developed to reduce exposure to harmful substances and to minimize the effects associated with these exposures. WHMIS covers compressed gases as well as reactive and corrosive materials, oxidizing agents (e.g., O₂),

flammable or combustible materials, and poisonous and infectious substances. For more information, contact the Occupational Health and Safety Department at the Ministry of Labour.

6.4.3 Reference Values

Reference values used must be documented for each facility.

Appropriate predicted or normal values are necessary if meaningful interpretations of pulmonary function studies are to be made. There are many predicted values in the literature from which to choose. When selecting the best reference values for the facility, a number of factors are considered.

Predicted values with a large pool of both male and female subjects that vary in age (from 20-80 or so) and height are preferable. The population of subjects should be heterogeneous across towns and cities, socioeconomic status, religion, and occupation. The equipment and techniques for test procedures and calculations are similar to those used in the facility.

To determine if the reference values selected are suitable, test 10-20 non-smoking healthy male and female subjects of varying ages and heights and apply the predicted values to the data. If the results are within the accepted ranges of normal for each test, then the reference values were properly chosen.

Reference values should be consistent over time.

The decision to correct for racial or ethnic background of the patient rests with the Quality Advisor and may be based on the proportion of such patients studied in the facility. On the other hand, the decision may be not to incorporate these corrections into the normative predictive equations but consider the effects in the interpretation. Further discussion on this subject is available in the statement by the American Thoracic Society (ATS) (“Interpretation Strategies for Lung Function Tests”; ERJ 2005, 26; 948-968) and in the 2005 ATS manual.

6.4.4 Biologic Control

A biologic control is a healthy, non-smoking individual who has no known lung disease; these individuals must be available for repeated testing and typically work in the facility. Testing of these individuals on a regular basis is recommended to ensure reproducible results over time, particularly in “black box” systems that cannot easily be calibrated.

6.5 Electrical Safety

All equipment used at the facility must be CSA approved.

Staff should learn how to correctly operate and care for the electrical equipment used in the facility. Cords, plugs, and outlets are routinely checked for damage. All receptacles are of the three-prong type. If any piece of electrical equipment appears to operate in an abnormal manner (strange noises or hums, sparks, fuzzy tracings, etc.) it must be removed and repaired by a qualified person. If possible, do not touch an electrical device with one hand and a patient with the other hand.

6.6 Infection Control

Resources are available through the **Provincial Infectious Diseases Advisory Committee** of Public Health Ontario, *Infection Prevention and Control for Clinical Office Practice June 2013*
http://www.publichealthontario.ca/en/eRepository/IPAC_Clinical_Office_Practice_2013.pdf

Note: Facilities should visit the website at least annually, during the review of their policies and procedures manual, to obtain the most recent updates.

Nosocomial infections are a potential risk during pulmonary function testing. A clean mouthpiece and nose clip is used for each patient. Disposable bacterial filters are to be used unless the circuitry is changed after each patient.

Most infectious diseases are transmitted by direct contact with contaminated equipment or an airborne route. An infection control program to reduce the risk of transmission to an acceptable level – realizing that zero risk is not attainable – includes:

- reprocessing used equipment
- routine practices
- droplet precautions (for febrile and severe respiratory illness)
- airborne transmission precautions (for tuberculosis)

6.7 Cleaning, Disinfection and Sterilization of Equipment

6.7.1 Cleaning

Cleaning is the first important step in reprocessing equipment. Effective cleaning will maximize the efficacy of any subsequent disinfection or sterilization process. An item that is not properly cleaned cannot be disinfected or sterilized with assurance.

Effective cleaning can physically remove a large number of microorganisms. Soil or other foreign material can shield and protect microorganisms or even interact to neutralize the action of the disinfectant or sterilant. Furthermore, after glutaraldehyde treatment, which acts as a fixative, any organic material left on the item is extremely difficult to remove.

The cleaning of used and contaminated equipment consists of the following:

- Sorting and soaking
- Removal of organic material
- Rinsing
- Drying

6.7.2 Disinfection and Sterilization

There are many materials and methods for disinfecting and sterilizing equipment. Manufacturers' recommendations should always be followed. Pulmonary function equipment is classified as semi-critical items and requires high-level disinfection. For detailed information regarding cleaning, disinfection and sterilization of medical instruments please refer to the **Provincial Infectious Diseases Advisory Committee of Public Health Ontario** at http://www.publichealthontario.ca/en/eRepository/IPAC_Clinical_Office_Practice_2013.pdf

If equipment is contaminated with blood or sputum it must be sterilized immediately after it is used. Some chemicals will sterilize faster if they are heated. To eliminate toxic chemical residues, equipment is thoroughly rinsed and air dried before reusing.

Equipment that cannot be subjected to heat or chemicals must be sterilized using ethylene oxide (gas sterilization). The equipment must be thoroughly cleaned and packaged before it is sterilized. Equipment sterilized by this method must be aerated for approximately 48 hours (or less if heat is applied) before use.

6.8 Infection Control Program

Infection control consists of evidence-based practices and precautions used to prevent the transmission of pathogens causing infection, and includes the knowledge and skills required to implement appropriate interventions. Infection control practices are intended to protect patients, health care workers, and the public from exposure to infectious diseases. The infection control program is designed to reduce the risk of transmission to an acceptable level – realizing that zero risk is not attainable – by taking the appropriate isolation precautions.

6.8.1 Routine Practices

Routine practices describe the system of practices recommended by Health Canada (Standard Precautions is the counterpart term used by the US Centers for Disease Control and Prevention) which incorporates the blood borne pathogen precautions or Universal Precautions (UP) and non-blood borne pathogen precautions or Body Substance Precautions (BSP). Routine practices are designed to reduce the risk of transmission of pathogens from blood, all body fluids, secretions, excretions, and drainage of wounds from all patients (are considered potentially infectious) regardless of infection status.

Routine practices, or its equivalent, should be used during all patient care, and includes:

- Hand washing or cleansing with an alcohol based sanitizer before and after any direct contact with a patient.
- The use of additional barrier precautions to prevent health care worker contact with a patient's blood, body fluids, non-intact skin or mucous membranes.
- The wearing of surgical masks and eye protection or face shields where appropriate to protect the mucous membranes of the eyes, nose and mouth during procedures and patient care activities likely to generate splashes or sprays of blood, body fluids, secretions, and excretions.

- Gloves are to be worn when there is a risk of body fluid contact with hands; gloves should be used as an additional measure, not as a substitute for hand washing.
- Gowns are to be worn during procedures and patient care activities likely to generate splashes or sprays of blood, body fluids, secretions, and excretions that could contaminate uniform or clothing.

6.8.2 Droplet Precautions

Droplet precautions describe the type of precaution designed to reduce the risk of droplet transmission of infectious diseases. Droplet transmission involves contact of the mucous membrane of the eyes, nose, and mouth of a susceptible person (host) with large particle droplets containing pathogenic microorganisms generated from a person who exhibits a clinical disease or who is a known or suspected carrier of the pathogenic microorganism (source). The source person generates these droplets from coughing, sneezing, talking, or performing pulmonary function tests. Transmission via large particle droplets requires close contact between the source person and susceptible host because these droplets (larger than 5 μm in size) do not remain suspended in the air and generally travel through the air short distances of 1 meter (3 feet) or less. In addition to routine precautions, droplet precautions should be used for a patient with known or suspected to have a droplet transmitted infection.

Droplet precautions consists of:

- Placing the source person in a single room if possible, or separated from other people by at least 1 meter and minimizing the time spent in the waiting room.
- Wearing a water resistant surgical or procedural mask and eye protection or face shield.

6.8.3 Airborne Precautions

Airborne precautions describe the type of precaution designed to reduce the risk of airborne transmission of infectious diseases. Airborne transmission occurs by dissemination of airborne droplet nuclei (smaller than $5 \mu\text{m}$ in size) evaporated from larger droplets or dust particles containing microorganisms that remain suspended in the air for long periods of time. Microorganisms carried in this manner can be widely dispersed by air currents and inhaled by susceptible hosts over a longer distance (in the same room or different rooms) from the source person. There is evidence of airborne transmission of source patients with tuberculosis.

Airborne precautions consist of:

- Patients suspected of having active pulmonary TB should not have pulmonary function tests until this diagnosis is excluded.
- Placing and confining the patient with known or suspected infectious tuberculosis in an examining room keeping the door closed at all times. This room should have negative pressure relative to the surrounding areas with exhaust vented outside or filtered through high-efficiency filters if recirculated to other areas in the facility.
- Wearing special high-efficiency masks with adequate facial seal (N95 respirator) when entering room of patient with known or suspected infectious pulmonary tuberculosis.

Because pulmonary function laboratories may be asked to evaluate individuals with symptoms consistent with active pulmonary tuberculosis (TB), transmission to other patients and health care workers remains a potential risk. TB remains an important potential occupational hazard in health care facilities that serve populations at high risk (including Aboriginal Canadians, the inner city poor, or emigrants from countries in Asia, Eastern Europe, Africa and Latin America where TB is still common).

Recent U.S. reports have documented outbreaks of multi-drug resistant TB in health care facilities, and also the failure of these facilities to implement appropriate TB control measures. In these outbreaks, 18 to 35 percent of exposed workers had documented conversions on tuberculin testing; health care workers infected with HIV are particularly susceptible. A consistent contributing factor to nosocomial outbreaks is a delay in diagnosis, due to lack of physician awareness, atypical clinical presentations or inadequate diagnostic facilities. BCG does not confer complete protection; TB can still occur in vaccinated health care workers.

It is very difficult to estimate precisely the infectiousness of an index case, but infectiousness is higher if the patient has extensive disease on chest radiographs, positive sputum smears for acid-fast bacilli, or is not receiving effective therapy. A patient with frequent cough or who undergoes cough-inducing procedures is also thought to be more infectious.

All health care workers are under an ethical and legal duty to both protect the health of their patients and to maintain confidentiality. Staff with symptoms compatible with tuberculosis should seek advice from Occupational Health or from their own doctor so that they do not expose patients to infection.

Recent Canadian guidelines do not specifically address TB precautions in pulmonary function laboratories. By inference, however, recommendations might include:

- All staff should be aware of the infection control guidelines for patients with known or suspected tuberculosis.
- Patients suspected of having active pulmonary TB should not have pulmonary function tests until this diagnosis is excluded.
- When a patient with active tuberculosis is tested before the diagnosis is known, identification of the contacts in the Lab at the time of testing, and immediate notification of the Public Health Department are required.
- Lab personnel should undergo two-step tuberculin testing before employment and have regular tuberculin skin tests thereafter.

In pulmonary function labs that serve populations at high risk, appropriate ventilation strategies should be employed. The relative cost-effectiveness of adequate ventilation, ultraviolet light and personal masks/ respirators remains controversial. Front-line personnel should consider the use of high-efficiency particulate air filter (HEPA) masks.

6.9 Latex Anaphylaxis

Natural rubber latex is a common component of many medical supplies. Although most often associated with disposable gloves, other items which contain latex include airways, intravenous tubing, syringes and stethoscopes. The reporting of allergic reactions to latex has dramatically increased in the past 10 years. Frequent users of latex products may develop allergies to latex proteins, with resulting allergic reactions varying from mild to life-threatening.

6.9.1 Providing a Latex-Safe Environment

A latex-safe environment should be the goal of every health care facility. Latex has been used in the manufacture of pulmonary function circuits, and especially in disposable mouthpieces, nose clips and tubing. While reported reactions in exposed patients are rare, it would appear prudent to use latex-free products wherever possible. Emergency carts with latex-free medical products should be available.

6.10 Emergency Procedures

Emergency policies and procedures are documented in the facility manual and must include medical emergencies and fire safety.

6.10.1 Medical Emergencies

Each facility performing exercise testing and bronchoprovocative testing is equipped with a:

- sphygmomanometer
- stethoscope
- wheelchair
- oxygen source with mask
- connective tubing
- AED (staff properly trained to use it –BCLS)
- airway management equipment
- appropriate drugs – Salbutamol, Nitroglycerine

Note: *These medications are checked monthly for expiry dates on all drugs and sterile equipment.*

6.10.2 Fire Safety

It is each staff person's responsibility to be aware of the facility's policies and procedures with respect to fire safety and fire prevention. Common sense is stressed so that emergency exits are not blocked and fire barrier doors are not propped open. A fire manual is available and reviewed annually. It includes the responsibilities for fire prevention, the classes of fires and extinguishers, steps on discovery of a fire, plans for reporting fires, fire evacuation plans, and maps. Fire numbers are posted on all telephones. Appropriate fire extinguishers are easily accessible and are checked each month and replaced if outdated or used.

When a fire is discovered:

- remove patients from immediate danger
- enclose area, close doors and windows upon leaving
- turn lights on
- turn off gas cylinders
- activate alarm

- call fire department, give location, your name, and type of fire
- try to extinguish the fire only if it is feasible

An evacuation plan is prepared and is practised periodically

For specific fire safety prevention and evacuation procedures, contact your local fire department.

Independent Health Facilities: Clinical Practice Parameters and Facility Standards

Pulmonary Function Studies

Volume 2 Clinical Practice Parameters

Chapter 7 Oxygen Saturation by Pulse Oximetry

List of main abbreviations

COHb= carboxyhemoglobin	MetHb= methemoglobin
F _I O ₂ = inspired O ₂ fraction	P _a O ₂ = arterial partial pressure for O ₂
Hb= deoxyhemoglobin	P _A O ₂ = alveolar partial pressure for O ₂
HbO ₂ = oxyhemoglobin	SaO ₂ = arterial O ₂ saturation
HR= heart rate	SpO ₂ = O ₂ saturation by pulse oximetry

7.1 Overview

Oxygen saturation by pulse oximetry (SpO₂) is a non-invasive estimate of hemoglobin O₂ saturation using the absorption of different wave lengths of light from oxygenated (HbO₂) and deoxygenated (Hb) hemoglobin. Pulse oximeters have 2 LEDs (light emitting diodes) one in the red region (660nm) and one in the infrared region (940nm). Oxygenated hemoglobin absorbs more infrared light and allows more red light to pass through. Deoxygenated hemoglobin allows more infrared light to pass through and absorbs more red light. HbO₂ absorbs less light in the red region of the optical spectrum (660nm) than does Hb therefore reflecting it as red and oxygenated blood is distinctively red, whereas deoxygenated blood has a characteristic dark blue colour. The difference in transmission of 660nm vs 940nm wavelength can then be used to calculate the amount of oxygenated hemoglobin.

Determining SpO₂ allows for the non-invasive estimation and monitoring of blood oxygenation. Decreases in SpO₂ indicate the presence of hypoxemia, i.e. reduction in O₂ concentration within the arterial blood. Hypoxemia is a major cause of impaired tissue O₂ delivery and hypoxia (low tissue PO₂) as most of the O₂ available in arterial blood is bound to Hb. The SpO₂ is usually obtained from the fingertip, forehead, or earlobe at rest, exercise, or different levels of supplemental O₂. Many of the studies on pulse oximetry employed healthy volunteers (for derivation of calibration curves) and relatively few investigations were done in ambulatory patients with cardiopulmonary disease. Measurements obtained from a pulse oximeter are typically SpO₂ and pulse rate, which is equivalent to heart rate (HR). Common clinical applications of determining SpO₂ are at rest, sleep and exercise.

7.2 Prerequisites

There are no prerequisites for this test.

7.3 Indications

Indications for this test include the need to:

- estimate SpO₂ if there is a clinical suspicion of desaturation, in association with exertional dyspnea, lung disease or a reduced diffusing capacity
- document changes in SpO₂ with exercise, (usually in patient with SpO₂ >90% at rest)
- monitor changes in SpO₂ during sleep

- document improvement in oxygen desaturation following change in therapy or in level of O₂ supplementation with or without exercise

Note: Routine use of oximetry to determine oxygen saturation at rest without any clinical indication is not an appropriate standard of care.

7.4 Contraindications

Exercise oximetry should not be performed in patients with uncontrolled systemic hypertension, unstable angina pectoris, or those who have had a systemic or pulmonary embolism, or a myocardial infarction within the last four weeks.

7.5 Instrumentation

Pulse oximeter with a probe for attachment to a peripheral site (e.g., finger, ear, forehead). A probe for more than one site must be available.

7.6 Techniques

The patient should have refrained from smoking or from inhaling second hand smoke for one hour. Ask the patient if he/she has symptoms compatible with Raynaud's phenomenon. If that is the case, an ear or forehead transreflectance probe may be used. Apply the probe to a clean site. Consider heating the extremity where the probe will be applied as SpO₂ is dependent upon adequate arterial blood flow. Nail polish and/or artificial acrylic nails must be removed prior to testing. Do not use an inflated blood pressure cuff on the same limb as the oximeter probe. If SpO₂ was measured also during exercise, observe the patient for 3 to 5 minutes post exercise for cardiac or neurological signs or symptoms.

7.7 Measurements

SpO₂ and HR can be obtained from the digital display and printout. A hardcopy of measurements (print out or manual documentation) must be available. The plethysmographic waveform and signal strength indicator must be used to assess validity of the data. A comparison of pulse oximeter HR reading to one from palpation and an ECG, if available, can be used to check adequate perfusion at the probe site.

7.8 Reporting Guidelines

Resting oximetry is performed in the sitting position, if different, it must be documented

The inspired oxygen used by the patient (room air or supplemental oxygen) should be documented.

If SpO₂ is measured at a different levels of inspired O₂, then up to 20 minutes equilibration time may be required between determinations.

If saturation is continually monitored, a change in value of 4% between different levels of inspired O₂ or during exercise means that there has been a real change in saturation, but the significance requires clinical interpretation.

Report hypoxemia at rest and/or exercise if $SpO_2 \leq 88\%$.

Table 1: Key variables to be reported

Variable	Symbol	Unit	Comment
Oxygen saturation by pulse oximeter	SpO_2	%	
Heart rate	HR	bpm	
Supplemental O_2		%	for Venti-mask
		L/min	for nasal cannula

7.8.1 Limitations of Procedure

Substantial reductions in arterial partial pressure for O_2 (P_aO_2) can be missed by the isolated analysis of SpO_2 due to the sigmoid shape of the HbO_2 dissociation curve. P_aO_2 rather than SaO_2 is the main drive for ventilatory stimulation through the carotid bodies. A normal SpO_2 in the presence of an elevated inspired O_2 concentration provides little or no information on the adequacy of patient ventilation. In fact, owing to the curvilinear relationship between alveolar (A) ventilation and “mean” P_AO_2 plus the presence of substantial (A-a) O_2 gradient there is an inherent delay for P_aO_2 to reflect acute decreases in P_AO_2 induced by hypoventilation. For these reasons, oxygen saturation cannot be used to determine the adequacy of patient ventilation.

Situations or outside interference may affect pulse oximeter readings, limit precision or limit the performance of a pulse-oximeter instrument (**Table 2**).

- Motion artifact can interfere with pulse oximeter measurements. Some pulse oximeters are better than others at rejecting motion artifact.
- COHb falsely elevates SpO_2 values; high MetHb values cause falsely low values on pulse oximeters when the O_2 saturation is $>85\%$, and falsely high values when O_2 saturation is $<85\%$.
- Low perfusion states from vasoconstriction.
- Nail polish or acrylic nail coverings can alter oximetry readings when a finger probe is used; black, blue, and green nail polish significantly lower readings. It is recommended that any nail polish be routinely removed before finger probes are used for pulse oximetry measurement.
- Inability to detect saturations below 83% with the same degree of accuracy and precision as at higher saturations.
- Inability to quantify the degree of hyperoxemia present.
- Hyper-bilirubinemia has been shown NOT to affect the accuracy of SpO_2 readings.

- Skin pigmentation may be associated with slightly elevated saturation values.

Table 2: Factors known to interfere with pulse oximetry at the point-of-care

• Inadequate peripheral perfusion
• Incorrect probe position
• Nail varnish (specially acrylic)
• Atrial fibrillation and other possible arrhythmias
• Insufficient warming
• Motion-related artefacts
• Carboxyhaemoglobin
• Methaemoglobin-induced bias towards 85%
• Overestimation in some patients with sickle cell disease
• Intravenous dyes
• Increased venous pulsation (tricuspid incompetence)
• External electrical and optical interference

7.8.2 Validation of the Oximeter

Oximeter validation annually by a Biomedical Facility equipped with an oximeter simulator is strongly recommended.

7.8.3 Normal values for oximetry(2)

Resting SpO₂ on room air for:

Age (18-44) ≥ 96%

Age (45-64) ≥ 94%

Age (>64) ≥ 93%

7.9 Quality Control

A self check routine for the functionality of the oximeter is initiated when the unit is switched on. The operator should not use the oximeter if the self-check routine has failed.

With conventional pulse oximetry, the instruments are generally accurate to as low as 83% saturation when patients are being tested under steady state conditions. When using the older standard oximeters,

check the manufacturers' recommendations for accuracy ranges. Skin thickness and skin pigmentation can affect the results obtained from oximetry.

For the saturation to accurately reflect steady state conditions, the patient must be continuously breathing a given F_iO_2 for a minimum of 5 minutes and possibly as long as 20 minutes, depending on the degree of airflow limitation, prior to the measurement being recorded.

Biologic controls should be monitored and documented monthly.

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Chapter 8 6-Minute Walk Test (6MWT)

List of main abbreviations

6MWT: 6- minute walk test	MCID: minimal clinically-important difference
6MWD: 6- minute walking distance	SpO ₂ : O ₂ saturation by pulse oximetry
HR: heart rate	

8.1 Overview

The 6-minute walk test (6MWT) is commonly used to assess response to a medical or surgical intervention in subjects with moderate to severe heart or lung disease and to evaluate functional capacity. It is a simple test that assesses patients' ability to walk without sophisticated equipment (1). The test is reproducible (8%) and simple to perform. The 6MWT might provide a good index of the ability to carry out daily activities. The information from the 6MWT is complimentary to **Cardiopulmonary Exercise Testing**, the test of choice to determine maximal exercise capacity and the mechanisms of exercise limitation (**See Chapter 15, Cardiopulmonary Exercise Testing**).

8.2 Pre-requisites

8.2.1 Facility Requirements

- A 30 m-long, unobstructed (clear of obstacles and traffic) and straight-line walking course must be available
- The walking course should be marked at 3-meter intervals
- Orange traffic cones should be placed at the starting (0-meter) and 30-meter turnaround points
- Testing should be performed in a location where a rapid, appropriate response to an emergency is possible.
- The appropriate location of a crash cart should be determined by the physician supervising the facility.
- Supplies that must be available include O₂, sublingual nitroglycerine, aspirin, and salbutamol (metered dose inhaler or nebulizer). A telephone or other means should be in place to enable a call for help.

8.3 Indications

Exercise-related O₂ desaturation

- Interstitial lung disease
- COPD

Functional Status

- COPD
- Interstitial lung disease

- Heart failure
- Peripheral vascular disease

Predictor of morbidity and mortality

- COPD
- Heart failure
- Pulmonary hypertension

Pre-treatment and post-treatment comparisons

- Lung surgery
- Pulmonary rehabilitation
- Pulmonary hypertension
- COPD
- Heart failure

8.4 Contra-Indications

8.4.1 Absolute:

- unstable angina during the previous month
- myocardial infarction during the previous month

8.4.2 Relative:

- resting heart rate of more than 120 beats/min,
- systolic blood pressure of more than 180 mmHg,
- diastolic blood pressure of more than 100 mmHg.

Patients with any of these findings should be referred to the physician ordering or supervising the test for individual clinical assessment and a decision about the conduct of the test. The results from a resting electrocardiogram done during the previous 6 months should also be reviewed before testing. Stable exertional angina is not an absolute contraindication for a 6MWT, but patients with these symptoms should perform the test after using their antiangina medication, and rescue nitrate medication should be readily available.

8.5 Indications for test termination

- chest pain
- intolerable dyspnea
- leg cramps
- staggering
- diaphoresis (sweating)
- pale or ashen appearance

8.6 Instrumentation and Supplies

- Pulse Oximeter
- Countdown timer (or stopwatch)
- Lap counter (mechanical or counter on worksheet)
- Two small orange cones to mark the turnaround points
- A chair or wheelchair for patient to sit in an emergency
- Worksheets on a clipboard
- A source of O₂ with nasal cannula
- Sphygmomanometer and stethoscope

8.7 Technique

8.7.1 Pre-Test Procedures

- Physicians are not required to be present during all tests. However, the supervising laboratory physician may decide whether physician attendance at a specific test is required.
- Check physician's order for 6 MWT with or without supplemental O₂.
- When switching from room air to supplemental O₂ or vice and versa, a minimum of 10 minutes should be elapsed before starting the walk test.
- Comfortable clothing with walking shoes (sneakers)
- Patients should use their usual walking aids during the test (cane, walker, rollator etc.)
- Patients should take their medications as usual
- No meals and no vigorous exercise within 2 hours before test
- Patients should not wear nail polish or artificial acrylic nails
- Height and weight must be accurately measured
- Patient should rest for at least 10 minutes in a chair near the starting point. During the 10 minutes rest, attach the oximeter probe to ensure that the SpO₂ and heart rate (HR) signals are acceptable and optimal. Using Exercise Oximetry Worksheet (*see pg 53*), record at least the last 5 minutes of SpO₂ and HR readings.
- Before walking start, rate and record patient's dyspnea (shortness of breath) level using the Borg Scale (*see pg 51, Borg Scale*) while patient is standing at the starting point.
- A "warm-up" period before the test should not be performed.
- Carefully explain to the patient the objective of the test and state clearly that ***"The object of this test is to walk as far as possible for 6 minutes. You will walk back and forth in this hallway. You are permitted to slow down, to stop, and to rest as necessary. You may lean against the wall while resting, but resume walking as soon as you are able."***

8.7.2 Test Procedure

- Do **not** walk with the patient unless patient is a fall risk even with the walking aids.
- Do **not** talk to anyone other than the patient during the walk.
- Watch the patient and do not get distracted and lose count of the laps.

- Keep conversation to the minimum. **Use an even tone of voice to communicate with the patient for concerns or words of encouragement.**
- Record the SpO₂ and HR at a periodic time interval (e.g.: 30 seconds interval) and when every lap is completed (*see Exercise Oximetry Worksheet pg 53*).
- Patient is allowed to rest if needed to and resume walking as soon as patient is able to continue (number of rests are recorded).
- At the end of 6 minute mark, stop the patient and note the distance of the partial lap walked in meters. Rate and record patient's dyspnea level using the Borg Scale immediately.
- If O₂ supplementation is needed during the walks and serial tests are planned, then during all walks by that patient O₂ should be delivered in the same way with the same flow. If the flow must be increased during subsequent visits due to worsening gas exchange, this should be noted on the worksheet and considered during interpretation of the change noted in 6MWD.
- The type of O₂ delivery device should also be noted on the report: for instance, the patient carried liquid O₂ or pushed or pulled an oxygen tank, the delivery was pulsed or continuous, or a technician walked behind the patient with the oxygen source (not recommended).
- Measurements of pulse and SpO₂ should be made after waiting at least 10 minutes after any change in oxygen delivery.

8.7.3 Post-procedure

- Ask the patient to sit and rest in a chair for recovery; continue to monitor the SpO₂ and HR for 2 minutes. Remove oximeter probe if the 2-minute post walk SpO₂ and heart rate are returning close to the pre walk values.
- Calculate the 6-min walk distance (6MWD) from adding the total laps walked multiply the distance per lap (e.g. 30 m) and the partial distance walked in meters at the end of 6 min mark.

8.8 Reporting Guidelines

- See Sample of Exercise Oximetry Report pg 54.
- Report HR from low to high values for the duration of the walk
- Report the SpO₂ from high to low for the duration of the walk
- Calculate the 6MWD and compare it against the lower limit of normal and percent predicted.

8.9 Interpretation

A sample of reference values is provided below: note that the lower limit of normal (LLN) is at least 100 m below the predicted value. Absolute values are also valuable to predict mortality and severe dysfunction: a value <350 m has been widely used in this context in patients with COPD (7).

6MWD Reference Value for aged 40 – 80 (Enright PL, 1998)

Male:
 Predicted = $(7.57 \cdot \text{Ht}) - (5.02 \cdot \text{A}) - (1.76 \cdot \text{Wt}) - 309$
 LLN: (Predicted -153)

Female:
 Predicted = $(2.11 \cdot \text{Ht}) - (2.29 \cdot \text{Wt}) - (5.78 \cdot \text{A}) + 667$
 LLN: (Predicted -139)

6MWD Reference Value for age 68 years and older (Enright PL, 2003)

Male:
 Predicted = $493 + (2.2 \cdot \text{Ht}) - (0.93 \cdot \text{Wt}) - (5.3 \cdot \text{A}) + 17$
 LLN: (Predicted - 100)

Female:
 Predicted = $493 + (2.2 \cdot \text{Ht}) - (0.93 \cdot \text{Wt}) - (5.3 \cdot \text{A})$
 LLN = (Predicted * 0.75)

Where:

Ht = Height in centimeter (cm)

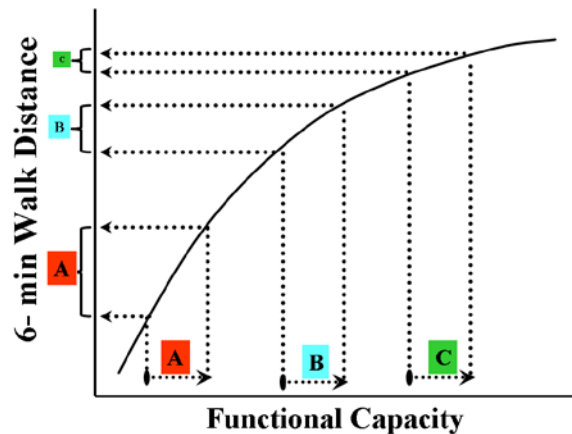
Wt = Weight in kilogram (kg)

A = Age in years

LLN = Lower limit of normality

Although an influential first study suggested that the minimal clinically-important difference (MCID) for the 6-MWD was in the range of 50-80 m in patients with COPD (8), more recent data indicate that it might be as low as 25-30 m in more severe patients (6,7,9). In fact, a reduction in the 6MWD of 30 m or more has been associated with increased risk of death in these patients (7). Similar MCID values have been reported in interstitial lung disease and heart failure (10). It should be noted, however, that the test becomes less sensitive to unravel the effects of interventions as the patients walks longer at baseline (or improve over time)(Figure 1).

Figure 1: Impact of similar changes in functional capacity (FC) (arrows) according to patient's baseline 6-min walk distance (6-MWD). Due to the curvilinear relationship between FC and 6-MWD, the 6-MWD tends to become less sensitive the greater the baseline value.



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Chapter 9 Exercise Oximetry for Home Oxygen Assessment

List of main abbreviations

6MWT: 6-minute walk test	HR: heart rate
6MWD: 6- minute walk distance	SpO ₂ : O ₂ saturation by pulse oximetry

9.1 Overview

Home Oxygen Program (HOP) is administered through the Assistive Devices Program (ADP) under the Ministry of Health and Long-Term Care. Its mandate is to provide consumer centered support and funding to Ontario residents who have long-term physical disabilities to provide access to personalized assistive devices appropriate for the individual’s basic needs. Its goal is to provide funding assistance for the rental of appropriate home oxygen equipment and supplies in order to correct or minimize hypoxemia resulting in improved health and increased participation in activities of daily living. (Home Oxygen Therapy - Policy and Administration Manual, Assistive Devices Program, Ministry of Health and Long-Term Care, Page 7, April 2014)

Note: It is the intent of the CPSO, Independent Health Facilities program to provide technical guidance on exercise testing for hypoxemia based on "Home Oxygen Therapy - Policy and Administration Manual, April 2014". The Facility must stay current with any updates and revisions published by Assistive Devices Program, Ministry of Health and Long-Term Care, Ontario.

Medical Eligibility Criteria for home oxygen:

- Chronic hypoxemia at rest, on room air:
 - Age ≥ 19: PaO₂ ≤ 55 mmHg or SaO₂ ≤ 88%
 - Age ≤ 18: SpO₂ ≤ 88%
- Persistent PaO₂ (56-60 mmHg) or SaO₂ (89-90%) on room air with any one of the following conditions:
 - Cor pulmonale
 - Pulmonary Hypertension
 - Persistent Erythrocytosis (polycythemia)
 - Exercise limited by hypoxemia and documented to improve with supplemental Oxygen
 - Nocturnal hypoxemia

Medical Eligibility Criteria for Hypoxemia on Exercise (Home Oxygen Program - Policy and Administration Manual, Assistive Devices Program, Ministry of Health and Long-Term Care, April 2014)

- Hypoxemia on exercise is defined as exertional saturation less than or equal to 88%.
- Funding for individuals who exhibit Hypoxemia on exercise is available only to:
 - those with hypoxemia on exercise whose exercise tolerance is restricted due to severe breathlessness and for those who are motivated to improve their daily activity level using oxygen therapy. Severe breathlessness is defined as Grade 4 or greater on the Medical Resource Council Dyspnea Scale (see Canadian Thoracic Society COPD Guidelines)
 - those who do not qualify under the Medical Eligibility Criteria for Hypoxemia at rest. Documentation of non-hypoxemia at rest may include ABG or resting Oximetry Study.
 - those with $SpO_2 < 80\%$ on walking with oxygen, regardless of dyspnea or distance walked
 - those with improved exercise tolerance with oxygen defined as one of the following:
 - a. $SpO_2 \leq 88\%$ on walking for five (5) minutes or more on room air, increase walked distance by 25% on oxygen along with an improvement of at least one unit in the Borg score at the end-exercise point of the shortest test
 - b. $SpO_2 \leq 88\%$ on walking for less than five (5) minutes on room air, increase walked time by a minimum of two (2) minutes on oxygen along with an improvement of at least one unit in Borg score at end-exercise point of the shortest test.

9.2 Prerequisites

Oxygen saturation at rest on room air:

Age ≥ 19 : $PaO_2 > 55$ mmHg or $SaO_2 > 88\%$ or $SpO_2 \geq 88\%$

Age ≤ 18 : $SpO_2 > 88\%$

Facility Requirements

- A 30 m-long, unobstructed (clear of obstacles and traffic) and straight-line walking course must be available
- The walking course should be marked at 3-meter intervals
- Orange traffic cones should be placed at the starting (0-meter) and 30-meter turnaround points
- Testing should be performed in a location where a rapid, appropriate response to an emergency is possible.
- The appropriate location of a crash cart should be determined by the physician supervising the facility.
- Supplies that must be available include oxygen, sublingual nitroglycerine, aspirin, and salbutamol (metered dose inhaler or nebulizer). A telephone or other means should be in place to enable a call for help.

9.3 Indications

- Shortness of breath on exertion with Grade 4 or higher on the MRC Dyspnea Scale
- Suspected exercise-related O₂ desaturation
- Interstitial lung disease
- COPD
- Other chronic lung diseases

9.4 Contra-Indications

9.4.1 Absolute:

- unstable angina during the previous month
- myocardial infarction during the previous month

9.4.2 Relative:

- resting heart rate of more than 120,
- systolic blood pressure of more than 180 mm Hg,
- diastolic blood pressure of more than 100 mm Hg.

Patients with any of these findings should be referred to the physician ordering or supervising the test for individual clinical assessment and a decision about the conduct of the test. The results from a resting electrocardiogram done during the previous 6 months should also be reviewed before testing. Stable exertional angina is not an absolute contraindication for a 6MWT, but patients with these symptoms should perform the test after using their anti-angina medication, and rescue nitrate medication should be readily available.

9.5 Indications for Test Termination

- chest pain
- intolerable dyspnea
- leg cramps
- staggering
- diaphoresis (sweating)
- pale or ashen appearance

9.6 Instrumentation and Supplies

- Oximeter
- Countdown timer (or stopwatch)
- Lap counter (mechanical or counter on worksheet)
- Two small orange cones to mark the turnaround points
- A chair or wheelchair for patient to sit in an emergency
- Worksheets on a clipboard
- A source of oxygen with nasal cannula
- Small tank of compressed air with flow meter
- Small tank of oxygen with flow meter

- Sphygmomanometer and stethoscope

9.7 Techniques and Measurements

9.7.1 Pre-Test Procedures

- Physicians are not required to be present during all tests. However, the supervising laboratory physician may decide whether physician attendance at a specific test is required.
- Comfortable clothing with walking shoes (sneakers)
- Patients should use their usual walking aids during the test (cane, walker, rollator etc.)
- Patients should take their medications as usual
- No meals and no vigorous exercise within 2 hours before test
- Patients should not wear nail polish or artificial acrylic nails
- Height and weight must be accurately measured

9.7.2 Test Procedures

- Patient should rest for at least 10 minutes in a chair near the starting point.
- During the 10 minutes rest, attach the oximeter probe to ensure that the SpO₂ and heart rate (or pulse rate) signals are acceptable and optimal and nasal cannula with compressed air set at 4 L/min. Since HOP prefers the study to be single-blinded, the technologist **should not** tell the patient he/she is receiving the compressed air. Instead, the technologist should tell the patient he/she is receiving a different level of oxygen. Some labs cover the compressed air tank to avoid patient recognition that the tank is compressed air. Compressed air can be mounted on a rollator or a light weight wheeled oxygen cart.
- Using the Worksheet (*see pg 49*), record at least the last 5 minutes of SpO₂ and heart rate readings.
- While standing at rest at the starting point, rate and record patient's dyspnea (shortness of breath) level using the Borg Scale (*see pg 51*).
- Patients should use their usual walking aids during the test (cane, walker, rollator etc)
- Do not walk with the patient unless patient is a fall risk even with the walking aids.
- Do not talk to anyone other than the patient during the walk.
- Watch the patient and do not get distracted and lose count of the laps.
- Keep conversation to the minimum. Use an even tone of voice to communicate with the patient for concerns or words of encouragement.
- Record the SpO₂ and heart rate at a periodic time interval (e.g.: 30 seconds interval) and when every lap is completed.
- Patient is allowed to rest if needed to and resume walking as soon as patient is able to continue (number of rests are recorded).

Note: Do not tell the patient he/she is receiving the compressed air. Instead, tell the patient he/she is receiving a different level of oxygen.

Patient walked for 6 minutes and SpO₂ > 88% with compressed air

- At the end of 6 minute mark, stop the patient and note the distance of the partial lap walked in meters. Rate and record patient's dyspnea level using the Borg Scale immediately.
- Ask the patient to sit and rest in a chair for recovery; continue to monitor the SpO₂ and heart rate for 2 minutes. If the 2-minute post walk SpO₂ and heart rate are returning close to the pre walk values, remove oximeter probe and patient can be discharged.

Patient walked less than five (5) minutes and SpO₂ ≤ 88% with compressed air

- Patient is stopped whenever a sustained SpO₂ is equal to or less than 88% whichever comes first, Record the time walked, rate and record patient's dyspnea level. A sustained SpO₂ value is reached when the same value is displayed and recorded twice at a sampling rate of 30-second intervals.
- Switch the compressed air to 100% oxygen cylinder and set the flow rate at 4 L/min and allow patient to breathe the oxygen for at least 10 minutes.
- Once the patient is rested enough and ready to repeat the walk test, record at least five (5) minutes of resting SpO₂ and heart rate. Record the resting Borg Scale while standing at the starting line just before patient starts walking
- The patient should walk an extra two (2) minutes from the time walked with compressed air. Borg Scale should be obtained while patient is still walking, at the same time when he/she stopped with compressed air.

Note: After setting the O₂ flow rate to 4 L/min, allow the patient to breathe the oxygen for at least 10 minutes before repeating the test.

Patient walked five (5) minutes and more and SpO₂ ≤ 88% with compressed air

- Patient is stopped whenever a sustained SpO₂ is equal to or less than 88% whichever comes first. Record the time walked, rate, and record patient's dyspnea level. A sustained SpO₂ value is reached when the same value is displayed and recorded twice at a sampling rate of 30-second intervals.
- Switch the compressed air to 100% oxygen cylinder and set the flow rate at 4 L/min and allow patient to breathe the oxygen for at least 10 minutes.
- Once the patient is rested enough and ready to repeat the walk test, record at least five (5) minutes of resting SpO₂ and heart rate. Record the resting Borg Scale while standing at the starting line just before patient starts walking
- The patient should walk an additional 25% of the distance walked with compressed air. Borg Scale should be obtained while patient is still walking, at the same time when he/she stopped with compressed air.

9.7.3 Calculations

- Calculate the distance walked from adding the total laps walked multiply the distance per lap (e.g. 30 meters) and the partial distance walked in meters at the end of the walk.

9.8 Reporting Guidelines

- See pg 54 Sample Exercise Oximetry Report
- Resting SpO₂ must be recorded with a minimum of 10 minutes rest.
- When switching from room air to supplemental oxygen or vice and versa, a minimum of 10 minutes should elapse before starting the walk test.
- Resting Borg Scale should be rated and recorded while standing.
- Report the low and high values (range) of SpO₂ and Heart Rate for the duration of the walk test
- Calculate the walk distance.
- Compare the walk distance against predicted 6MWD, Lower Limit of Normal and percent predicted.

Note: Home Oxygen Assessment protocol for exercise duration is not limited to "six (6) minutes", the interpreting physician must interpret percent predicated accordingly when the walking time exceeds six (6) minutes.

9.9 Interpretation

Interpreting physician must familiar with the current protocol and eligibility criteria set by the Home Oxygen Program, Assistive Devices Program, Ministry of Health and Long-Term Care (See Fig. 1 Flow Chart for Exercise Oximetry for Home Oxygen Assessment).

Fig. 1 Flow Chart for Exercise Oximetry for Home Oxygen Assessment

Exercise Oximetry for Home O₂ Assessment

(Assistive Devices Program, MOH, April 2014)

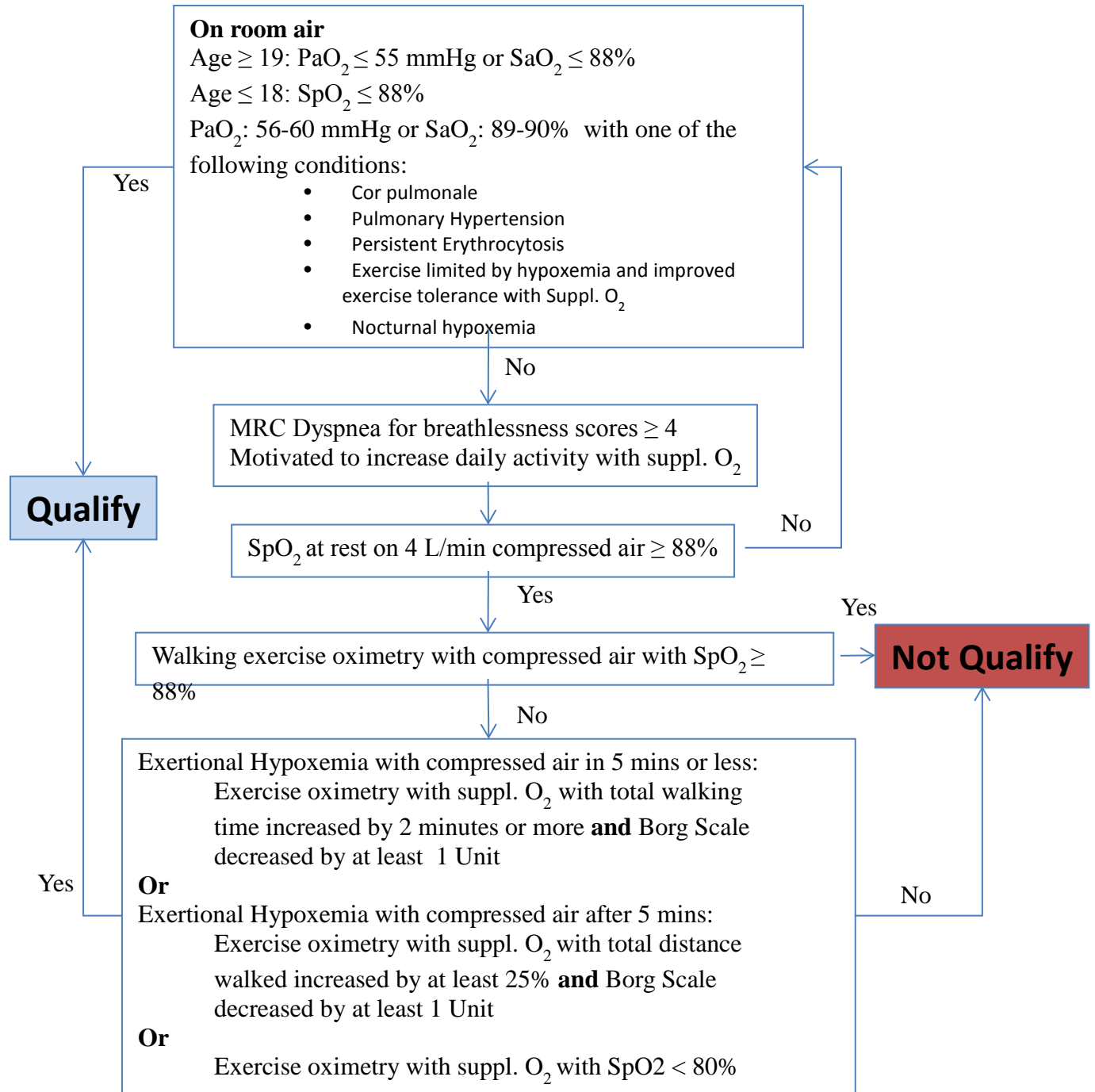


Fig. 2 Borg Scale

Dyspnea Grade

Please grade your level of shortness of breath from 0 – 10 using the scale below

Borg Scale

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

Fig. 3 Exercise Oximetry Worksheet

- 6-MWT
 Room Air Supplemental O2 ____ L/min (%) Nasal Prongs Mask
 Home O2 Assessment
 Compressed air (4L/min) Supplemental O2 (4L/min) Nasal Prongs Mask

	Activity	Timer (m:s)	SpO2 (%)	Pulse Rate (HR, b/m)	Lap Counter (1 Lap = 30 meters)	
Borg Scale Rest (Standing)	Rest (Sitting)	8:00			1	16
	Rest (Standing)	9:00			2	17
	Standing	9:30			3	18
	Standing	10:00			4	19
	WALK	0:30			5	20
Borg Scale Exercise	↓	1:00			6	21
		1:30			7	22
		2:00			8	23
		2:30			9	24
		3:00			10	25
		3:30			11	26
		4:00			12	27
		4:30			13	28
		5:00			14	29
		5:30			15	30
	STOP	6:00				
	RECOVERY	7:00				
		7:30				
		8:00				
Rest Counter: 1 2 3 4 5 6 7 8 9 10					+	M
Tech comments: Walked with <input type="checkbox"/> cane <input type="checkbox"/> walker <input type="checkbox"/> rollator					Total Distance Walked = #Lap ____ *30 + ____ meters = ____ meters	

Fig. 4 Sample of Exercise Oximetry Report

6-MWT
 Room Air Supplemental O2 ____ L/min (%) Nasal Prongs Mask
 Home O2 Assessment
 Compressed air (4L/min) Supplemental O2 (4L/min) Nasal Prongs Mask

	Level 1	Level 2
Inspired supplemental O ₂ (L/min)		
Rest SpO ₂ (%)		
HR (b/min)		
Borg Scale (0-10)		
Exercise SpO ₂ (range: high – low)		
HR (range: low – high)		
Borg Scale (0-10)		
Distance Walked (meters)		
Distance Predicted (meters)		
Distance % Predicted		
Distance (Lower Limit of Normal)		
Total Time Walked (m:s)		
% Change from Level 1		
Number of Rests		

Tech comments: Walked with <input type="checkbox"/> cane <input type="checkbox"/> walker <input type="checkbox"/> rollator
Physician Interpretation:

References

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Chapter 10 Carbon Monoxide Diffusing Capacity

List of main abbreviations

BHT- breath hold time	VI-Inspired Volume
COHb-Carboxyhemoglobin	KCO- Transfer Coefficient (D_LCO / V_A)
D_LCO - Carbon Monoxide Diffusing Capacity	V_A -Alveolar Volume
RGA – Rapidly Responding Gas Analyzer	

10.1 Overview

Carbon monoxide diffusing capacity (D_LCO) is a non-invasive measurement of the transfer of carbon monoxide (CO) from the alveoli to the pulmonary capillaries per minute for each mm Hg pressure gradient for CO. The single-breath determination of D_LCO is the most widely used and standardized method. The D_LCO is affected by both the resistance to diffusion presented by the lung itself and by the rate of carbon monoxide (CO) uptake by hemoglobin in the pulmonary capillaries. In addition, D_LCO is influenced by the lung volume in which the tracer gas and CO distributes. Therefore, the D_LCO may be abnormal in conditions associated with decrease in the number of alveolar units receiving CO, loss of alveolar-capillary membrane area, membrane thickening, change in lung perfusion and ventilation-perfusion imbalance. D_LCO measurements are used in the diagnosis and management of obstructive, restrictive, and pulmonary vascular diseases. There is a wide variance among the published reference equations for determining normal values for D_LCO as well as inter-facility differences in testing equipment and technique(1)(2).

10.2 Prerequisites

The patient should refrain from smoking on the day of the test. The patient should not eat a large meal for at least 2 hours or exercise vigorously within an hour before the test. Supplemental oxygen should be discontinued for at least 10 minutes before testing upon approval from the ordering physician or the Medical Director/Quality Advisor. To ensure safety and undue respiratory distress of the patient, oxygen saturation should be monitored by the pulse oximeter while patient is disconnected from supplemental oxygen (*see Appendix VI Sample Patient Prep Instructions*).

10.3 Indications

Indications for this test include the need to:

- establish the presence of parenchymal lung disease in patients with an obstructive ventilatory impairment (e.g., differentiating asthma from underlying emphysema)
- establish the presence of parenchymal lung disease in patients with a restrictive ventilatory impairment (e.g., differentiates intrinsic lung disease (decreased D_LCO and D_LCO / V_A) from an extra-pulmonary process (decreased D_LCO but normal or increased D_LCO / V_A))

- establish the presence of parenchymal lung disease in patients with otherwise normal pulmonary function studies (e.g., asbestosis, fibrosing alveolitis, drug-induced or radiation pneumonitis, pneumocystis pneumonia)
- suggest the presence of pulmonary vascular disease (e.g. hypoxemia despite normal spirometry and lung volumes)
- assess disease severity in patients with parenchymal or pulmonary vascular disease
- estimate functional impairment and/or disability
- help monitor progression of parenchymal lung disease or assess its response to therapy
- help monitor patients with pulmonary hemorrhage syndromes (increased D_LCO and D_LCO / V_A)

10.4 Contraindications

There are no contraindications for this test. Relative contraindications may include mental confusion, poor muscular coordination, or an inability to adequately seal lips on the instrument's mouthpiece.

10.5 Instrumentation

The equipment for D_LCO testing is as follows:

- a spirometer or pneumotachometer linear over an 8 L volume range and with a $\pm 3.0\%$ volume accuracy ($\pm 3.5\%$ accounting for testing syringe accuracy of $\pm 0.5\%$)
- a single sample (ss) or continuous real-time (crt) gas analyzer system linear from zero to full span within $\pm 1.0\%$ such as an infrared absorption gas analyzer (ss/crt for CO methane (CH₄)), thermal conductivity analyzer (ss for CO, helium (He), and neon (Ne)), fuel cell (ss for CO), multi-gas LED (Light Emitting Diode) analyzer (crt for CO and CH₄)
- or rapid gas analyzer system with 0-90% response time of ≤ 150 ms, maximum non-linearity $\pm 1\%$ of full scale, accuracy within $\pm 1\%$ of full scale, interference from 5% carbon dioxide or 5% water vapor ≤ 10 ppm error in [CO], drift for carbon monoxide ≤ 10 ppm over 30 s and drift for tracer gas $\leq 0.5\%$ of full scale over 30s. Flow accuracy must be within $\pm 2\%$ over the range of -10 to +10L/s. Volume accuracy (3-L syringe check) must be within ± 75 mL. Barometric pressure sensor accuracy must be within 2.5%. The system must have the ability to perform a QA check (3-L syringe; ATP mode; inhaling ~ 2 L test gas). The system must sample and store data by digitising at ≥ 100 Hz per channel with ≥ 14 bit resolution.
- Circuit resistance must be < 1.5 cmH₂O/L/s up to 6 L/s. If a demand valve is used on a compressed test gas cylinder, the maximum inspiratory pressure required for 6 L/s inspiratory flow through both the circuit and the valve must be < 9 cmH₂O.
- Equipment dead space volume for both inspired test gas and the alveolar sample must be known and their role in all data computation algorithms must be identified and documented. The system must be leak free.

- a bag-in-box system (consisting of a valve system with separate bags for inspired dry test gas and exhaled alveolar sample) with circuit resistance < 1.5 cm H₂O at a flow of 6 L/s or a demand valve (and a compressed gas source) with sensitivity < 10 cm H₂O for 6 L/s flow
- a compressed gas cylinder of test gas mixture consisting of 0.3% CO, the appropriate inert tracer gas (10% He, 10% Ne, or 0.3% CH₄), 21% oxygen (O₂), and balance nitrogen (N₂)
- a carbon dioxide (CO₂) absorber and a water (H₂O) absorber or H₂O vapour permeable tubing) if CO₂ and H₂O interfere with gas analyzer performance
- a timing device accurate to ± 1% over 10 s (100 ms)
- an automatic data acquisition and computation system (i.e., computer)
- a hemoglobin (Hb) measurement and carboxyhemoglobin (COHb) measurement is highly recommended

10.6 Technique

The patient should be sitting quietly for 5 minutes before starting the test and remain seated throughout the test. For patients on continuous O₂ therapy, the ordering physician or Medical Director/Quality Advisor should be consulted before it is removed. If clinically acceptable, the supplemental O₂ should be discontinued for a minimum of 10 minutes prior to testing with continuous oximetry measurement to ensure that the change is tolerated.

The patient is connected to the D_LCO system and breathes quietly. After at least 3 stable breaths, the patient exhales slowly to residual volume (RV). When at or near RV, the patient inhales rapidly (in less than 4 s) to total lung capacity (TLC) so that the inspired volume (VI) is ≥90% of the largest vital capacity (VC). The patient breath holds for approximately 10 s (± 2 s), relaxing against a closed valve. During the breath-hold time (BHT), ensure that no expiratory effort against a closed airway (Valsalva manoeuvre) and no inspiratory effort against a closed airway (Mueller manoeuvre) is made. The Valsalva manoeuvre generates excessive positive intrathoracic pressure and the Mueller manoeuvre generates excessive negative intrathoracic pressure that may decrease and increase the D_LCO , respectively. After the BHT, the patient exhales at a moderate speed (< 4 s) in order to wash out the dead space of 0.75 to 1.0 L or 0.5 L for VC < 2.0 L and collect an alveolar gas sample of 0.5 to 1.0 L (collection time < 3 s).

A minimum of 4 minutes must be allowed between manoeuvres to allow for adequate elimination of test gas from the lungs. The subject should remain seated during this interval. In patients with airflow obstruction, a longer period (e.g. 10 min) should be considered. Several deep inspirations during this period may help clear test gases more effectively.

With RGA systems, for complete washout, the tracer gas level at end-exhalation must be ≤2% of the tracer gas concentration in the test gas. End expiratory tracer gas concentration must be reported and used to adjust the tracer gas concentration data used in the determination of V_A at the beginning of breath-holding.

10.7 Measurements

Criteria for Acceptability:

A VI $\geq 90\%$ Of the largest VC in the same test session; alternatively, a VI $\geq 85\%$ of the largest VC in the same test session and V_A within 200ml or 5% (whichever is greater) of the largest V_A from other acceptable manoeuvres.

85% of test gas VI inhaled in <4 s.

A stable calculated breath-hold for 10 ± 2 s with no evidence of leaks or Valsalva/Mueller manoeuvres during this time

Sample collection completed within 4 s of the start of exhalation. For RGA systems, virtual sample collection should be initiated after dead-space washout is complete.

Criteria for Repeatability

At least 2 acceptable D_LCO measurements within 2 ml/min/mmHg of each other

Quality Control Grading:

Score	VI/VC	Breath-Hold Time	Sample Collection
A	$\geq 90\%^*$	8-12 s	≤ 4 s
B	$\geq 85\%$	8-12 s	≤ 4 s
C	$\geq 80\%$	8-12 s	≤ 5 s
D	$\leq 80\%$	<8 or >12 s	≤ 5 s
F	$\leq 80\%$	<8 or >12 s	>5 s

Only Grade A manoeuvres meet all acceptability criteria * (or VI/VC $\geq 85\%$ and V_A within 200mL or 5% {whichever is greater} from another acceptable manoeuvre). The average D_LCO values from two or more Grade A manoeuvres that meet the reproducibility criterion should be reported. If only 1 Grade A manoeuvre is attained, the D_LCO value from that manoeuvre should be reported. If no Grade A manoeuvre is obtained, manoeuvres of grades B to D might still have clinical utility. The average of such manoeuvres should be reported but these deviations from the acceptability criteria must be noted to caution the interpreter of the test results. Manoeuvres of Grade F are not useable.

If a current Hb is available, the D_LCO should be adjusted to a value standardized to a Hb of 146 g/L for adult and adolescent males and 134 g/L for adult female and children < 15 years old.

The D_LCO test should yield the following:

- a VI of $\geq 90\%$ of the largest VC
- the BHT determined using the Jones and Mead method (i.e., the alveolar contact time starts $1/3$ after the inspired volume has been completed and ends when $1/2$ the expired sample has been collected)

- actual or ratios of initial (i.e., test gas) and final (i.e., alveolar) CO and tracer gas concentrations
- the alveolar volume (V_A) by single breath dilution of the tracer gas
- uncorrected D_LCO from the average of acceptable tests
- corrected D_LCO for Hb
- D_LCO / V_A ratio (K_{CO}) representing the D_LCO per unit lung volume (involved in diffusion)
- D_LCO should be adjusted if COHb is greater than 2%

10.8 Reporting Guidelines

Table 3: Key variables to be reported

Variable	Symbol	Units
Carbon monoxide diffusing capacity (“transfer factor”)	D_LCO	mL/min/mmHg
Alveolar volume	V_A	L
Carbon monoxide diffusing capacity corrected by alveolar volume	D_LCO/V_A or K_{CO}	mL/min/mmHg/L

- Technical comments must identify test components that do not meet ATS/IHF criteria.
- The average of at least two acceptable D_LCO tests should be reported with the predicted and percent-predicted D_LCO . Any adjustments for Hb and COHb concentration should be reported.
- The average V_A (BTPS) and predicted V_A should be reported. V_A represents the lung volume in which the tracer gas and CO distributes and then the CO transfers across the alveolar-capillary membrane. Hence, the D_LCO measurement must be interpreted in relation to only its V_A and not a separately determined V_A or total lung capacity (TLC) from more accurate techniques.
- Increased K_{CO} (or D_LCO/V_A) can be found in cases of discrete loss of gas exchanging units (e.g., consolidation, collapse, localized infiltrate), incomplete alveolar expansion (pleural, neuromuscular, chest wall, poor technique), alveolar hemorrhage and increased pulmonary blood volume (left-to-right shunt, increased cardiac output)
- The average VI at BTPS should be reported.
- The D_LCO should be interpreted with caution in patients with FEV1 below 1 L or in those who have smoked within two hours prior to testing.

10.9 Quality Control

- Volume calibration check must be performed daily using a 3-L syringe discharged at least three times to give a range of flows varying between 0.5 and 12 L/s (with 3-L injection times of ~6 s and ~0.5 s) [Examples: low flow (0.5 – 2.0 L/s); medium flow (2-6 L/s); high flow (8-12 L/s)] The volume at each flow rate must meet the accuracy

requirement of $\leq 2.5\%$. Thus, after injecting 3 L into a spirometer, the volume should be within 3 ± 0.075 L or (2.92 – 3.08 L) at each flow rate.

- For continuous real-time gas analysis, a two-point calibration of the infrared analyzer using zero and test gas concentration to within $\pm 0.5\%$ of test gas is required before each test. Hence, the analysis of 0.3% CO should be within $\pm 0.0015\%$ of the true value.
- For gas chromatography analysis, separation of the test gas concentration into its component gases and detection by a thermal conductivity analyzer to give a single chromatograph tracing with a Ne and CO peak (i.e., a “one point” determination) is required before each test.
- For infrared CO analyzers with electronic linearization and He analyzers, a linear response (i.e., when the analyzer is adjusted to zero and full scale using the test gas concentration) is established before each test. Linearity check using a minimum of three serial gas dilutions or primary standards (maximum error of no more than $\pm 0.0015\%$) is required every three months.
- Flow and gas analyzers must be zeroed prior to each manoeuvre. After each manoeuvre, a new zeroing procedure must be carried out to account for analyzer drift during the previous test.
- Biologic control must be performed weekly. The standard subject’s weekly D_LCO should be less than 12% or less than 3 ml/min/mmHg from the established mean value.
- Calibration syringe D_LCO check must be done weekly. A simulated D_LCO test using a 3-L calibrating syringe as a “test subject” in the normal patient test mode. The syringe is attached to the mouth port of the instrument and then emptied after a few “normal tidal breaths” and then filled with 3 L of test gas. After 10-second “breath hold”, the syringe is then emptied. Additional dead space of mouthpiece, filter and connectors must be considered and included in the system setup configuration to aid the V_A calculation. The simulated D_LCO value must be < 0.5 ml/min/mmHg. The simulated V_A must be within 300 ml of 3 L times the ATPD to BTPS correction factor, which is $310/(273+T)*(PB/(PB-47))$, whereas T is ambient temperature in Celsius and PB is barometric pressure in mmHg.
- Calibration syringe leak test must be done monthly
- Linearity check (calibration syringe or simulator) must be completed monthly.

References

1. Macintyre N et al. 2005. Standardisation of the single-breath determination of carbon monoxide uptake in the lung. *Eur Respir J.* 26:720–735.
2. ATS Pulmonary Function Laboratory Management and Procedure Manual, Third Edition, 2016. Chapter 10.
3. 2017 ERS/ATS standards for single-breath carbon monoxide uptake in the lung. Brian L. Graham, et al. *Eur Respir J* 2017; 49: 1600016
4. Instrument Accuracy and Reproducibility in Measurements of Pulmonary Function. Robert L. Jensen, et al. *Chest* 2007; 132:388-395

Chapter 11 Functional Residual Capacity (FRC)

List of main abbreviations

EEL	End Expiratory Level
ERV	Expiratory Reserved Volume
FRC(He)	Functional Residual Capacity by Helium dilution
FRC(N ₂)	Functional Residual Capacity by Nitrogen washout
FRC(Pleth)	Functional Residual Capacity by Body Plethysmography
RV	Residual Volume
TLC	Total Lung Capacity
\dot{V}	Flow
VC	Vital Capacity
V _{TG}	Thoracic Gas Volume by Body Plethysmography

11.1 Overview

Functional Residual Capacity (FRC) is the static volume of gas remaining in the lungs at the end of a relaxed normal exhalation or the end of expiratory tidal breath. The end of a relaxed normal exhalation level also refers as the end-expiratory level (EEL) at zero flow. Once the FRC is measured, other lung volumes, such as Total Lung Capacity (TLC), Residual Volume (RV) and RV/TLC ratio can be calculated from the measurements of Inspiratory Capacity (IC), Vital Capacity (VC) and Expiratory Reserved Volume (ERV).

FRC may be measured by either gas dilution techniques or body plethysmography (1),(2). The two commonly used gas dilution methods both require the use of a physiologically inert gas that is relatively insoluble in blood and tissues. FRC (He) measurement by helium dilution requires a closed circuit system and involves the wash in and equilibration with a trace concentration of helium. Whereas FRC (N₂) by nitrogen washout is an open system, the resident gas (nitrogen) is replaced by breathing 100% oxygen usually via a demand valve.

Body plethysmography measures the thoracic gas volume (V_{TG}) at the end of a tidal breath, with appropriate correction of the end-expiratory level at zero flows, and thereby it is equivalent to FRC and termed as FRC (Pleth). Plethysmography measures all compressible gas in the thorax and is more accurate than the dilution methods. Measurement of FRC (Pleth) is not affected by poorly or non-ventilated areas of the lungs. The most common type of plethysmograph for clinical use is the constant-volume, variable-pressure box, though other types can be used.

Note: FRC measured by gas dilution techniques maybe underestimated in patients with moderate to severe airway obstruction due to gas trapping when compared to the FRC measured by the body plethysmography.

11.2 Testing Pre-requisites

Before plethysmography is performed, ensure that the patient is not claustrophobic. Spirometry is properly performed and the results are known prior to determining the FRC.

11.3 Testing Indications

Indications for this test include the need to:

- establish/confirm a restrictive ventilatory defect
- establish/confirm hyperinflation and gas trapping
- monitor progression of lung disease or assess its response to therapy
- differentiate types of lung disease processes characterized by flow rates and capacities measured by spirometry
- make preoperative assessments when surgical procedure is known to affect lung function

11.4 Contraindications

Discontinuation of supplemental oxygen or interruption of IV medications may be contraindicated in some patients. Check with physician prior to testing.

Relative contraindications for performing static lung volumes include all those considered for spirometry. The relative contraindications for forced expired manoeuvres are the following:

- If a patient has a pneumothorax and testing is required the QA/Lab Director decides whether the pneumothorax is small and clinically stable in order to proceed with measurements. If measurements are done, results should take into account the pneumothorax
- Recent (within 6 weeks) myocardial infarction, or unstable cardiac status, ophthalmic surgery, abdominal surgery
- Significant ongoing hemoptysis
- Presence or suspected presence of active tuberculosis or other communicable respiratory disease (febrile and severe respiratory illness)

11.5 Instrumentation

11.5.1 Gas dilution methods

Pulmonary Function System with volume displacement/flow sensing spirometer, helium (He) analyzer (katharometer), or emission-type N₂ analyzer. Other systems derive the alveolar N₂ concentration from deduction of expired O₂ and CO₂ from oxygen and carbon dioxide analyzers respectively.

Compressed-gas cylinder (s) of test gas (s) used by the laboratory (e.g., 100% O₂, or 100% He, 21% O₂ with balance N₂).

Mouthpiece, tubing, nose clip, CO₂ and O₂ absorbers, and other miscellaneous equipment or supplies needed (e.g., facial tissue and chart paper).

11.5.2 Body Plethysmography

A body plethysmograph with a pneumotach for measuring flows < 2 L/second and two variable reluctance pressure transducers, one accurate to ± 2 cmH₂O for measuring box pressure and one accurate between ± 20 to 50 cmH₂O for measuring mouth pressure.

A computer or rapid recording instrument for displaying the slopes of \dot{V}/P_{box} and P_m/P_{box} is also required.

11.6 Technique

11.6.1 Helium Dilution

The patient is turned into the spirometer at the end expiratory level after stable tidal breaths (usually takes 5-8 breaths) is established. Instruct the patient to breathe normally until equilibrium of the helium occurs (approximately five minutes, it may take longer if patient is obstructed). Occasional slow inspiratory capacity manoeuvres may be done to speed the equilibration process. Oxygen is added to the system to replace what the patient consumes, either by the bolus method or the volume-stabilized method. Equilibration has occurred when the [He] changes $< 0.02\%$ in 30 seconds. The patient is instructed to perform a vital capacity (VC) manoeuvre, also known as slow vital capacity (SVC) either at the beginning or at the end of the trial so other lung volumes can be calculated. The patient is turned out of the system at the end-tidal point.

11.6.2 Nitrogen Washout

The patient is connected to the mouthpiece. When a stable tidal volume and respiratory rate are maintained, the patient is turned into the system such that 100% oxygen is inhaled from a demand valve or a reservoir. The end of the test is reached when $N_2 \leq 1.5\%$. The patient is instructed to perform a vital capacity manoeuvre, also known as slow vital capacity (SVC) either at the beginning or at the end of the trial so that other lung volumes can be calculated. The end expiratory nitrogen concentration is recorded as the alveolar nitrogen, although it likely underestimates the true alveolar nitrogen when there is significant airflow limitation.

11.6.3 Body Plethysmography

The patient is seated upright comfortably in the plethysmograph, breathes quietly through the mouthpiece apparatus with fingertips placed on both cheeks to prevent bulging of the cheeks to control measurement errors. When the end expiratory volume is stable, the mouth is occluded and the patient is instructed immediately to pant gently and shallowly against the closed shutter (a blockage) at a frequency of 1.0 Hz, the panting frequency should be within 0.5 and 1.5 Hz. An electronic metronome set at 1.0 Hz may be used to assist the patient to pant at the desired panting frequency.

The first preferred method, known as "linked" manoeuvre (without removing the mouthpiece), of measuring the ERV immediately after panting manoeuvres for FRC followed by a maximum slow inspiratory vital capacity (IVC) manoeuvre.

The second method is similar to the first; instead of performing ERV immediately after the panting manoeuvres for FRC, the patient is instructed to perform a maximum inspiratory capacity (IC) manoeuvre; followed by a maximum slow expiratory vital capacity (EVC) if the patient is able to continue

and following the instruction. If the patient cannot perform the slow EVC after the IC manoeuvre, a separate set of VC manoeuvres is needed to calculate the RV.

For patients with difficulties in understanding or following the instructions, or too dyspnoeic, a “non-linked” manoeuvre can be obtained by measuring FRC and IC-VC separately.

Note: *Body plethysmography may overestimate lung volumes in airflow obstruction. To minimize this effect, slow and gentle panting with supported cheeks should be observed.*

11.7 Measurements

11.7.1 Helium Dilution

Helium readings are recorded every 15 seconds until equilibration occurs. Equilibration is defined as no change greater than 0.02% helium in 30 seconds. IC (Inspiratory capacity), VC (Vital Capacity), and ERV (Expiratory Reserve Volume) are measured from the volume recording. Perform at least two technically satisfactory results. The mean values of the IC and FRC should be reported while the highest VC should be reported. The acceptable results of two FRC should agree within 10%, rounded to two decimal places. A minimum of 5 minutes should elapse between reported trials.

11.7.2 Nitrogen Washout

If the patient is on continuous supplemental oxygen, the patient must be able to breathe in room air for at least 15 minutes prior to the measurement. In most instances this will assume that alveolar nitrogen (N₂) is near 80%. Testing is continued until nitrogen concentration falls below 1.5% for at least three successive breaths. The volume is collected in the spirometer and its nitrogen concentration is measured. Perform at least two technically satisfactory measurements. Allow at least 15 minutes between each one. In patients with severe obstructive disease, time intervals between trials of less than 1 hour may produce invalid results (underestimation of lung volumes). The mean values of the IC and FRC should be reported while the highest VC should be reported. The acceptable results of two FRC should agree within 10%, rounded to two decimal places.

Note: *Perforated eardrum will cause significant errors in measurements; an earplug should be used whenever patient is identified.*

11.7.3 Body Plethysmography

Obtain at least three acceptable trials (consisting of 3-5 technically satisfactory panting with frequency between 0.5 and 1.5 Hz and the slope of P_m/P_{box} is within ± 10 cmH₂O and IC-VC manoeuvres) that agree within 5% of the mean and report the mean value. The highest two VC measurements should be within 0.15 L and within 5% of FVC for non-obstructive patients. The highest VC obtained should be reported. The reported value should be rounded to two decimal places.

11.8 Reporting Guidelines

Table 4: Key variables to be reported

Variable	Symbol	Unit
Functional Residual Capacity by Helium dilution	FRC(He)	L
Functional Residual Capacity by Nitrogen washout	FRC _{N₂}	L
Functional Residual Capacity by Body Plethysmograph	FRC(Pleth)	L
Vital Capacity	VC	L
Expiratory Reserved Volume	ERV	L
Inspiratory Capacity	IC	L
Total Lung Capacity	TLC	L
Residual Volume	RV	L
Residual Volume to Total Lung Capacity Ratio	RV/TLC	%

The report includes:

- results of baseline spirometry.
- identify type of FRC measurement method used (i.e., FRC_{N₂}, FRC(He) or FRC(Pleth)).
- reporting variables include FRC, TLC, RV, RV/TLC ratio and VC.
- each facility should select the reference standards which are most appropriate to their patient population as there are considerable differences in the predicted values for absolute lung volumes among the available studies.
- comparison of patient measurement to predicted normal values, using lower limit of normal (LLN) and 90% confidence interval to identify abnormal results.
- in the case of abnormal results, suggesting type of ventilatory abnormality based on other supporting measurements, such as spirometry, diffusing capacity and respiratory muscle strength.

11.9 Quality Control

Dilution Methods

- **Helium Dilution**

- The spirometer is physically calibrated every three months over the full range of the instrument and should be accurate over a 8L range to $\pm 3.5\%$ of the volume added. A daily 3L volume calibration (verification) and leak check is performed.
- A two point (zero to full scale) calibration of the helium analyzer is performed daily.
- Biologic controls must be monitored and documented on a monthly basis.
- **Nitrogen Washout**
- The spirometer is calibrated as above. The accuracy and linearity of the N₂ analyzer is checked before each patient by performing a 2-point calibration using zero and 80% nitrogen. A 3-point linearity check is required initially and every 6 months thereafter (0%, 40%, 80% nitrogen). If N₂ is derived from deductions of CO₂ and O₂, the respective analyzers must be checked according to the manufacturer.
- The pneumotach must be calibrated using room air for the inhaled check and O₂ for the exhaled check.
- Biologic controls must be monitored and documented on a monthly basis.
- **Body Plethysmography**
- Equipment calibration should be performed at least once daily before testing patients and every four hours during use. The box pressure transducer is calibrated using a 30-50 ml sine-wave pump. The mouth pressure transducer is calibrated using a water manometer and a calibration pump capable of generating 0 – 1.5 L/s for flow. An electronic signal to represent each of box pressure, mouth pressure, and flow can be used to represent the physical calibration. It is performed before each patient is tested. Volume-measuring-device calibration (verification) with a 3.0 L calibrating syringe should be performed daily.
- The box leak check and physical equipment calibration is performed monthly. Biologic controls must be monitored and documented on a monthly basis.

References

1. Standardisation of the measurement of lung volumes. Eur Resp J 2005; 26:511-522.
2. Pulmonary Function Laboratory Management Manual, Second Edition. Chapter 8. American Thoracic Society. 2004.

Chapter 12 Airway Resistance

List of main abbreviations

P _{box}	Box Pressure
P _m	Mouth Pressure
R _{aw}	Airway Resistance
sR _{AW}	Specific Airway Resistance
\dot{V}	Flow

12.1 Overview

Airway Resistance (R_{AW}) refers to the flow resistance in the airways between the mouth and alveoli. The body plethysmograph can be used to measure R_{AW} . This is advantageous as absolute lung volumes can be measured, allowing the calculation of a volume corrected (specific) resistance (sR_{AW}), or its reciprocal, conductance (sG_{AW}). The measurement of airway resistance is usually conducted at the FRC level and hence the R_{aw} represents the predominantly larger airways. Therefore, R_{AW} is insensitive in determining the presence of peripheral or small airway airflow limitation.

At present, there is no proven clinical role for the routine determination of Airways Resistance (R_{AW}). However, the inspiratory flow of the R_{AW} measurement may be reduced in patient with upper airway obstruction (1). Patients with obstructive lung disease are more appropriately followed with the flow volume loop.

12.2 Indications

Indications for this test include the need to:

- Further evaluate airflow limitation when spirometry does not meet acceptability criteria.
- Determine the response to bronchodilator.
- Determine bronchial hyperactivity in response to methacholine or histamine.
- Monitor the response to treatment.

12.3 Relative contraindications

- Mental confusion, muscular incoordination, body casts, or other conditions that prevent the patient from entering the plethysmograph or adequately performing the required manoeuvres (i.e., panting against a closed shutter).
- Claustrophobia that may be aggravated by entering the plethysmograph.
- Presence of devices or other conditions, such as continuous intravenous infusions with pumps or other equipment that will not fit into the plethysmograph, that should not be disconnected, or that might interfere with pressure changes (e.g. chest tubes).
- Continuous O₂ therapy that should not be temporarily disconnected.

- If a patient has a pneumothorax and testing is required the QA/Lab Director decides whether the pneumothorax is small and clinically stable in order to proceed with measurements. If measurements are done, results should take into account the pneumothorax.

12.4 Instrumentation

A body plethysmograph with a pneumotach for measuring flows < 2 L/second and two variable reluctance pressure transducers, one accurate to ± 2 cm H₂O for measuring box pressure and one accurate between ± 20 to 50 cm H₂O for measuring mouth pressure.

A computer or rapid recording instrument for displaying the slopes of \dot{V}/P_{box} and P_m/P_{box} is also required.

12.5 Technique

The patient, seated upright comfortably in the plethysmograph, breathes quietly through the mouthpiece apparatus with fingertips placed on both cheeks to prevent bulging to control measurement errors. When the tidal breathing is stable (usually within 5-8 breaths), the patient is instructed to pant shallowly and evenly (panting volume is within 50 - 100 ml) at a frequency (f) of 1.5 Hz but not greater than 2 Hz ($1.5 < f < 2$) with the shutter assembly open. The shutter is then closed and the patient continues to pant at the same frequency. An electronic metronome set at 1.5 Hz may be used to assist the patient to pant at the desired panting frequency.

12.6 Measurements

When the shutter is open, \dot{V}/P_{box} measurements are taken. When the shutter is closed, P_m/P_{box} measurements are taken. The panting volume should be within 50 – 100 ml with the panting frequency within 1.5 – 2.0 Hz. The slope of \dot{V}/P_{box} should be within 0.5 L/second. R_{AW} is calculated from the ratio of open-and-closed-shutter tangents (slopes) for each manoeuvre. Reported R_{AW} should be averaged from a minimum of three acceptable manoeuvres that agree within 10% of the mean value.

12.7 Reporting Guidelines

Table 5: Key variables to be reported

Variable	Symbol	Unit
Airway Resistance	R_{AW}	cmH ₂ O/L/sec

The reported R_{aw} and related indices are:

- calculated from the ratio of open- and closed-shutter tangents for each manoeuvre.
- averaged from three to five separate, acceptable manoeuvres (which may require as many as eight to ten trials).

- calculated with the open shutter tangent (Flow/Box Pressure) measured between flows of +0.5 to -0.5 L/s. For loops that display hysteresis, the inspiratory limbs may be used and the report needs to contain a comment noting this.
- compared to predicted normal values, using confidence intervals to identify normal results.

Report of test results must contain a technologist's statement about test quality, patient's understanding of testing process, and, if appropriate, which criteria were not achieved.

12.8 Quality Control

Equipment calibration should be performed at least once daily before testing patients and every four hours during use. The box pressure transducer is calibrated using a 30-50 ml sine-wave pump. The mouth pressure transducer is calibrated using a water manometer and a calibration pump capable of generating 0 – 1.5 L/s for flow. An electronic signal to represent each of box pressure, mouth pressure, and flow can be used to represent the physical calibration. It is performed before each patient is tested. Volume-measuring-device calibration (verification) with a 3.0 L calibrating syringe should be performed daily.

The box leak check and physical equipment calibration is performed monthly. Biologic controls must be monitored and documented on a monthly basis.

References

1. Pulmonary Function Laboratory Management Manual, Second Edition. Chapter 9. American Thoracic Society. 2004

Chapter 13 Methacholine Challenge Test

List of main abbreviations

FEV ₁ – Forced expired volume in one second
PD ₂₀ – Provocative delivered dose of methacholine to produce a 20% fall in FEV ₁
PC ₂₀ – Provocative concentration of methacholine to produce a 20% fall in FEV ₁
PC ₄₀ – Provocative concentration of methacholine to provide a 40% fall in sGaw
Raw – Airway Resistance
sGaw – Specific airway conductance

13.1 Overview

Airway hyperresponsiveness is one of the features that may contribute to the diagnosis of asthma. Airway responsiveness may vary over time, increasing during exacerbations and after allergen exposure, and decreasing in response to allergen avoidance strategies or treatment with inhaled or systemic steroid therapy.

Non-specific bronchial provocative testing involves inhaling a pharmacologic agent in doubling dilutions to induce diffuse airway narrowing in a controlled manner until either the maximum concentration or delivered dose has been inhaled, or a 20% fall in FEV₁ has occurred. Methacholine is generally used, and histamine was in the past as direct challenge test. Currently, Provocholine[®] and Methacholine Omega[®] are the only products approved by Health Canada and must be used.

The traditional nebulizer (English Wright) for 2-minute method and nebulizer (DeVilbiss 646) for 5-breath dosimeter method recommended in 1999 ATS Guidelines are no longer available. However, there are facilities that continue to use the 2-minute method with their remaining stock of English Wright Nebulizers.

In 2017, the European Respiratory Society (ERS) published the [ERS Technical Standard on Bronchial Challenge Testing](#)⁹ to address the issues of nebulizers and performance of methacholine challenge test. Summary of major recommendations are as follows:

1. Report the effective delivered (cumulative) dose of methacholine (provocative dose (PD₂₀)) instead of methacholine concentration (provocative concentration (PC₂₀)) causing a 20% fall in forced expiratory volume in 1 second (FEV₁).
2. Deep-breath inhalation method (5-breath method) is not recommended due to bronchoprotective effect reducing the response sensitivity.
3. Nebulizer or dosimeter manufacturer must provide characterisation of the device output and particle size to allow construction of a table of concentration-dose steps for inhalation protocol. The particle size of the aerosols generated by the nebulizer should be ≤ 5µm.
4. Tidal breathing method is recommended with an inhalation period of 1 minute or more when using a breath-actuated or continuous nebulizer.
5. When using a dosimeter, a breath count is required to calculate the appropriate delivered dose.

6. Starting dose between 1 and 3 µg with subsequent doubling or quadrupling steps is considered safe provided that the subject has normal or near normal spirometry with no significant bronchodilator response.

Bronchoprovocation studies are most appropriate in the presence of a normal or near-normal lung function. Bronchoprovocation studies are difficult to interpret and may be dangerous in patients with significant airflow obstruction, in which situation pre-and post-bronchodilator testing (or a therapeutic trial e.g. inhaled steroids or leukotriene – antagonists) may be more appropriate.

Both the technologist AND the physician must be physically present in the IHF when a bronchial challenge is performed in order to respond quickly to an emergency. The physician must be appropriately trained to treat acute bronchospasm or cardiopulmonary emergencies, including the appropriate use of resuscitation equipment.

13.2 Prerequisites

Acceptable and reproducible spirometry (or airways resistance R_{aw}), must be performed and the results known prior to testing. A consent form describing the test procedure should be available for the patient or parent/legal guardian of the patient to read and they should have the opportunity to ask questions before signing the consent form. See sample Methacholine Challenge Test Consent Form in Appendix VII. Other conditions and medications that can affect bronchial hyper-responsiveness should be documented (see below):

13.2.1 FACTORS THAT INCREASE BRONCHIAL RESPONSIVENESS

Factor	Duration of Effect
Exposure to environmental antigens	1 – 3 weeks
Occupational sensitivities	Months
Respiratory infection	3 – 6 weeks
Air pollutants	1 week
Cigarette smoke	Uncertain*
Chemical irritants	Days to months
<p>*Studies of the acute effects of smoking on airway hyper-reactivity and methacholine challenge testing are not consistent. There is some evidence of a brief acute effect that can be avoided by asking subjects to refrain from smoking for a few hours before testing.</p>	

13.2.2 MEDICATIONS THAT DECREASE AIRWAY RESPONSIVENESS

Medications which inhibit the response to methacholine (generally bronchodilators) should be withheld before the test for their duration of action. A pre-test questionnaire should be administered to screen medications and medical history that may affect the challenge test. See sample Methacholine Challenge Pre-Test Questionnaire in Appendix VIII. As new medications frequently appear on the market it is the responsibility of the Quality Advisor to keep the list of medications to be withheld up to date. Particular care needs to be given to combination medications, especially when one half does not have to be withheld (e.g. steroid/LABA combinations). The time that these are withheld should be for the longest acting.

The following is a list of medication types that should be withheld for the listed time frames prior to initiation of the methacholine challenge test:

Inhaled medications:	Minimum withholding time (hours)
Short-acting beta-agonists (SABA) (e.g. salbutamol, terbutaline)	6 hours
Short-acting anticholinergics (e.g. ipratropium (Atrovent))	12 hours
Long-acting beta-agonists (LABA) (e.g. salmeterol, formoterol, vilanterol)	36 hours
Ultra-long-acting beta-agonists (e.g. indacaterol, vilanterol, olodaterol)	48 hours
Long-acting anti-muscarinic (LAMA)/Long-acting anticholinergics (LAAC) (e.g. aclidinium, tiotropium, glycopyrronium, umeclidinium)	≥168 hours (7 days)
Cromones (e.g. Cromolyn sodium)	Do not withhold
Corticosteroids	Do not withhold
Oral medications:	
Liquid theophylline	12 hours
Intermediate-acting theophylline	24 hours
Long-acting theophylline	48 hours
Leukotriene modifiers (e.g. monteleukast)	Do not withhold
Anti-histamines	Do not withhold
Corticosteroids	Do not withhold

CAUTION:

In patients receiving any beta-adrenergic blocking agent the responses to methacholine chloride can be exaggerated or prolonged, and may not reverse as readily with short acting beta agonists. A short acting anti-cholinergic must be available. Withholding of beta-adrenergic blocking agents or performing the challenge in patients taking such agents should be done with caution and only upon specific orders from the ordering physician.

As methacholine inhalation can cause coughing, it is prudent to avoid doing the test in patients with an acute respiratory illness to protect the person performing the test.

NOTE:

Caffeine and caffeine-related products no longer need to be withheld before a methacholine challenge as they have no effect of clinical significance.

13.3 Indications

Indications for this test include the need to:

- rule out airway hyperresponsiveness as an etiology for unexplained cough, dyspnea, wheeze or chest tightness in the currently symptomatic patient.
- objectively confirm airway hyperresponsiveness in patients with cough, dyspnea, wheeze or chest tightness, when spirometry is normal.
- follow airway responsiveness (PC₂₀) in patients suspected of having occupational asthma when the patient is at work and away from work.

13.4 Contraindications

13.4.1 Absolute:

Airflow limitation (FEV₁ < 60% predicted or < 1.5 L in adults)

Unstable cardiac status, heart attack or stroke in last 3 months

Uncontrolled hypertension, systolic BP > 200, or diastolic BP > 100

Known aortic aneurysm

Pneumothorax

Recent ophthalmic surgery (6 weeks)

Significant hemoptysis

Presence or suspected presence of active tuberculosis or other communicable respiratory disease

13.4.2 Relative:

Inability to perform acceptable-quality spirometry due to chest pain or other patient factors

Pregnancy

Nursing mothers

Current use of cholinesterase inhibitor medication (for myasthenia gravis)

Current use of beta-adrenergic blocking agent

13.5 Indications for Test Termination

Shortness of breath or patient discomfort

Decrease in FEV₁ ≥ 20% or > 40% decrease in sGaw

13.6 Equipment and Supplies

A re-usable calibrated nebulizer (English Wright) or a high-quality single-patient use nebulizer with known output for reproducible and standard aerosolization of the agent is required. Documentation of the nebulizer output with particle size $\leq 5 \mu\text{m}$ must be provided by the manufacturer. Documentation of the nebulizer (English Wright Nebulizer) output of 0.13 ml/min (+/-10%) must be done by the facility.

- For the tidal breathing method, English Wright nebulizer or a high-quality single patient use nebulizer or dosimeter.
- A source of compressed air, flow meter, and tubing.
- Timer
- Mouthpiece and nose clip
- A spirometry system that meets current American Thoracic Society standards (see Chapter 6)
 - If the patient is unable to perform reproducible spirometry, a body plethysmograph may be used to measure airway resistance (R_{aw}) as the indicative response parameter. (see Chapter 11)
- A short acting beta-agonist inhaler (e.g. salbutamol) and a short acting anti-muscarinic inhaler (e.g. ipratropium) for reversal of bronchoconstriction.

Exhalation filters must be used on the nebulizer to minimize the chance that the technician will be exposed to the methacholine aerosol. If no expiratory filter is used the testing room must have adequate ventilation (at least two complete air exchanges/hour).

13.6.1 Methacholine solutions

Dilutions of methacholine are prepared in sterile vials according to the Complete ATS –Recommended Dilution Schedule:

Doubling Concentrations Protocol:

0.03, 0.0625, 0.125, 0.25, 0.5, 1, 2, 4, 8, 16 (mg/ml)

Quadrupling Concentrations Protocol:

0.0625, 0.25, 1, 4, 16 (mg/ml)

13.6.2 Dose Calculation

With the availabilities of device output characteristic and particle size ($\leq 5\mu\text{m}$), the delivered dose can be calculated as follows.

Dose (μg) = Concentration in nebulizer in mg/ml x Output x Respirable Fraction x time in min x 1000

13.6.3 Example of English Wright Nebulizer from the Appendix D of 2017 ERS technical standard on bronchial challenge testing

1. Output rate by Breath simulator collected with a 16 mg/ml from a filter at the month = 0.19 mg/min
2. Respiratory Fraction = 1
3. Therefore, the delivered dose from a concentration of 16 mg/ml in 2 minutes would be:

$$0.19 \text{ mg/ml} \times 1 \times 2 \times 1000 = 380 \text{ } \mu\text{g}$$

4. For other dilutions:

$$\text{Dose } (\mu\text{g}) = (\text{Concentration in mg/ml} \div 16 \text{ mg/ml}) \times 380 \text{ } \mu\text{g}$$

Doubling Dose Protocol		Quadrupling Dose Protocol	
Concentration (mg/ml)	Dose (μg)	Concentration (mg/ml)	Dose (μg)
0.03	0.71	0.0625	1.48
0.0625	1.48	0.25	5.94
0.125	2.97	1	23.8
0.25	5.94	4	95
0.5	11.9	16	380*
1	23.8		
2	47.5		
4	95		
8	190		
16	380*		

*Note: Dose 380 μg has been rounded up to 400 μg for simplicity on the “CATEGORIZATION OF AIRWAY HYPER RESPONSIVENESS (AHR)” table for interpretation as “Borderline AHR”.

13.6.4 Example of Doubling and Quadrupling Dose Protocols for 1- minute tidal breath Methacholine Challenge Test using the AeroEclipse® Breath Actuated Nebulizer (from page 140, Appendix 12.5 of the ATS Pulmonary Function Laboratory Management & Procedure Manual 3rd Edition)

1. The nebulizer is operated from a gas regulator at an operating pressure of 50 psi and at a flow rate of 8 L/min.
2. Output rate by Breath simulator collected with a 16 mg/ml from a filter at the month =
 $2.70 \text{ mg/ml} \div 16 \text{ mg/ml} = 0.16875 \text{ ml/min}$
3. Respirable fraction (RF, droplets < 5 µg) = 0.76
4. $T_i/T_{tot} = 0.4$ for adult or large child (T_i = Inspiratory Time; T_{tot} = Total respiratory cycle time)
5. Delivered dose at 16 mg/ml for one minute would be:
 $\text{Output} \times \text{RF} = 0.16875 \text{ ml/min} \times 0.76 = 0.12825 \text{ ml/min}$
6. For other dilutions:
 $\text{Dose } (\mu\text{g}) = \text{concentration in nebulizer in mg/ml} \times 0.12825 \text{ ml/min} \times 1 \times 1000$

Doubling Dose Protocol		Quadrupling Dose Protocol	
Concentration (mg/ml)	Dose (µg)	Concentration (mg/ml)	Dose (µg)
0.015625	2	0.015625	2
0.03125	4	0.0625	8
0.0625	8	0.25	32
0.125	16	1	128
0.25	32	4	512
0.5	64		
1	128		
2	256		
4	512		

Methacholine must be diluted using a sterile sodium chloride (NaCl) solution (0.9%) with or without a preservative. If benzyl alcohol is used as a preservative, then concentrations >0.9% may cause small cracks to form in the plastic material of the Wright nebulizers. For further information on the preparation of methacholine from powder refer to the *ATS Pulmonary Function Lab Manual 3rd Edition Chapter 12, page 124-125*. Expiry (after reconstitution) is 2 weeks refrigerated (4 degrees Celsius) for Provocholine® and Methacholine Omega®.

A consent form describing the procedure and potential side effects must be carefully read and signed by the patient or parent/legal guardian of the patient prior to the challenge.

Resuscitation equipment with appropriate bronchodilator drugs and intubation equipment is mandatory.

13.7 Technique

13.7.1 Tidal breathing Method

The baseline FEV₁ must be obtained in accordance of the current ATS/ERS recommendations. The methacholine solutions must be removed from the refrigerator at least 30 minutes prior to testing to allow the solutions to equilibrate to room temperature because the temperature of the solution affects the nebulizer output. This involves two minutes of tidal breathing or 60 seconds for a higher output nebulizer from the nebulizer where the response parameter (usually FEV₁) is followed starting at 30 seconds after each dose and repeated at 90 seconds. Since there is cumulative effect of methacholine, the time interval between the starting of two serial doses is important and should be kept constant at 5 minutes. Obtaining a full FVC is not required if the FEV₁ is the only outcome, however, care should be taken to ensure that the maximum inspiration is reached. The highest acceptable FEV₁ between 30 seconds and 90 seconds interval of each dose should be reported. Doubling doses of methacholine are administered until the maximum dose is reached or a drop in FEV₁ of 20% is obtained. If sGaw or sRaw is measured, the test is stopped after there has been a 40% increase in sRaw, or the maximum concentration has been reached. Once the test is terminated, the patient is given a bronchodilator, if required, and the FEV₁ measured at 10 minutes to ensure that the FEV₁ has returned to within 10% of baseline before the patient leaves the facility.

13.7.1.1 Shortening the Test

Note: *The test must never be shortened in children.*

Doubling concentrations are recommended for research protocols. The number of doses administered can be reduced to save time in adults in doubling concentrations. This can be accomplished by starting at a higher dose, or increasing the difference in concentrations between doses. Hargreave and colleagues have suggested a guideline based on drug therapy and ventilator function, when diluent (saline) is the starting inhalation.

- If the patient's FEV₁ is >80% of predicted and does not fall by more than 10% after inhalation of the diluent and the patient takes no pulmonary medications, the starting dose can be as high as 1 to 2 mg/ml.
- If the patient takes bronchodilators, the starting dose can be 0.125 mg/ml.
- In all other instances and for children, the starting dose should be 0.03 mg/ml.
- If the FEV₁ falls less than 5% after a dose of methacholine then the next concentration may be omitted in adults.

Quadrupling increments is recommended for clinical testing. Quadrupling increments with only six (6) doses including diluent can be used to save time but it will result in a lower cumulative dose. If

the test is used to determine changes in airway reactivity following therapy in patients known to have asthma, using doubling doses will give more precise PD₂₀ values.

13.8 Measurements

FEV₁ is measured at 30 and 90 seconds after each inhalation. If plethysmography is used the sRaw is measured at 30 and 90 seconds after each dose.

At each dose, the highest FEV₁ (or sRaw) is reported from the acceptable manoeuvres.

13.9 Post Test Patient Assessment and Discharge Criteria

The degree of bronchoconstriction at test completion will affect the discharge management of the patient.

- If the FEV₁ has fallen less than 10% of the baseline, no bronchodilator is required. The patient can be discharged.
- If the FEV₁ has fallen by 10% or greater than the baseline, the patient should receive 200 mcg of fast-acting bronchodilator (Salbutamol) from a metered dose inhaler via a valve-holding device and repeat the spirometry after 10 minutes. If the post-bronchodilator FEV₁ is less than 10% of the baseline, the patient can be discharged. However, if the post-bronchodilator FEV₁ remains greater than 10% fall from baseline or the patient is symptomatic, administer a second set of fast-acting bronchodilator (Salbutamol) or Ipratropium bromide (Atrovent) and repeat the spirometry after 10 minutes.
- If the patient's post-bronchodilator FEV₁ does not return to less than 10% of baseline value despite the additional bronchodilator administrations the patient must be seen by a physician prior to discharge.
- If plethysmography is used Raw should return to within 10% of baseline values before discharge.

13.10 Data Analysis/Calculations

13.10.1 Spirometry Calculations

Results should be documented as the percent decrease in FEV₁ from baseline at each dosage level. Airway responsiveness is reported as the PC₂₀, the dose of methacholine needed to decrease the FEV₁ by 20%.

13.10.2 Plethysmography

If airways resistance is measured, the specific conductance at each dosage level is calculated, and the specific conductance (sGaw) reported. The dose of methacholine needed to decrease the sGaw by 40% is reported.

13.11 Reporting Guidelines

13.11.1 Key variables to be reported

Variable	Symbol	Units
Forced expired volume in one second at baseline and at each inhaled dose	FEV ₁	L
Methacholine concentration producing a 20% decrease in FEV ₁	PC ₂₀	mg/ml
Methacholine delivered dose producing a 20% decrease in FEV ₁	PD ₂₀	µg
For plethysmography : specific airways conductance at baseline and at each inhaled dose	sGaw	L/sec/cmH ₂ O/L
Methacholine concentration producing a 40% decrease in sGaw	PC ₄₀	mg/ml

Quantification of airway responsiveness (AHR) as recommended from 2017 ERS guidelines using PD₂₀ and based on 2 minutes of nebulization using English Wright nebulizer are interpreted as follows:

CATEGORIZATION OF AIRWAY HYPER RESPONSIVENESS (AHR)

PC ₂₀ (mg/ml)	PD ₂₀ (µg)	Interpretation*
>16	>400	Normal AHR
4-16	100-400	Borderline AHR
1-4	25-100	Mild AHR
0.25-1	6-25	Moderate AHR
<0.25	<6	Marked AHR

*Before applying this interpretation scheme, the following must be considered:

- baseline airway obstruction is absent
- spirometry quality is good
- there is substantial post challenge FEV₁ recovery
- If the FEV₁ does not fall by at least 20% after the highest concentration (e.g., 16 mg/mL) then the PC₂₀ should be reported as ">16 mg/mL" or after the highest dose (e.g., 400µg), the PD₂₀ should be reported as ">400 µg". If the FEV₁ falls by more than 20% after inhalation of the diluent, a PC₂₀ or PD₂₀ is not reported. Instead state "there was a significant decrease in FEV1 after inhalation of the diluent and methacholine was therefore not given. This is in keeping with an increase in airway responsiveness."

13.11.2 Plethysmography Measurement

If airway resistance is measured, the PC₄₀ should be reported. The above interpretation of borderline, mild, moderate and marked increases in airway responsiveness cannot be used. Non-asthmatic subjects have a PC₄₀ above 2 mg/ml, those with a PC₄₀ below 2 mg/ml have airway responsiveness that would be in keeping with a diagnosis of asthma.

13.12 Quality Control

A new nebulizer's (English Wright) output should be determined by full calibration prior to use. The corresponding flow rate necessary to deliver the appropriate output must be recorded and used consistently. Subsequent checks of nebulizer output every 6 months need only test the output at that flow rate. If output varies by more than 10% during verification a full calibration must be performed.

For initial verification, the challenge procedure must separate patients with normal airways from patients with hyper-responsive airways. This is done by performing the challenge on at least 3 non-asthmatic individuals, who should have no response, and 3 individuals known to have asthma.

Spirometers must be calibrated according to recommendations in Chapter 6.

Methacholine dilutions must be refrigerated at 4 degrees Celsius. Provocholine® and Methacholine Omega® may be stored for 2 weeks. Methacholine must be warmed to room temperature prior to use. Any unused solution remaining in the nebulizer must be discarded.

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Chapter 14 Exercise-Induced Bronchoconstriction Test

List of main abbreviations

ECG: electrocardiogram	MVV: maximal voluntary ventilation
EIB: exercise-induced bronchoconstriction	SpO ₂ : O ₂ saturation by pulse oximetry
FEV ₁ : forced expired volume in 1 second	\dot{V}_E : minute ventilation
HR: heart rate	\dot{V}_{O_2} : oxygen uptake

14.1 Overview

Airways drying and/or cooling associated with increased pulmonary ventilation (\dot{V}_E) during exercise may induce bronchoconstriction (usually 5-8 minutes after exercise cessation) in susceptible subjects. As expected, the major factors that determine the severity of exercise-induced bronchoconstriction (EIB) are the \dot{V}_E reached and sustained during exercise and the water content and temperature of the inspired air. The subject is asked to exercise at a standard percentage of their maximum heart rate (HR) or maximum \dot{V}_E and sustain that target workload for a period of time. Non-invasive parameters such as HR, blood pressure, and oxygen saturation by pulse oximetry (SpO₂) are measured and recorded.

Exercise induces airway narrowing in the majority of patients with asthma and can be used as a challenge test to make a diagnosis of EIB in subjects with a history of breathlessness during or after exertion. Such a diagnosis cannot always be made by a methacholine bronchoprovocation study and EIB cannot be excluded by a negative response to Methacholine (1-4). The diagnosis of EIB should be established by changes in the forced expiratory volume in one second (FEV₁) after exercise, not on the basis of symptoms. Symptoms that are often associated with vigorous exercise, such as shortness of breath, cough, wheeze, and mucus production, are neither sensitive nor specific for identifying those with EIB (5-7). Methacholine is a direct airway stimulus whereas exercise is indirect and appears to be more specific albeit less sensitive (3). It is shown that in elite athletes who exercise in cold environments (skiers) they may have EIB with a normal methacholine challenge test (1,2). It appears that EIB is an early manifestation of asthma and often supports a high level of airway mast cell presence (5). Exercise testing may also be used to determine the effectiveness of medications prescribed to prevent EIB and allow titration of dosing of medications (6,7).

A number of surrogates of EIB have been developed (eucapnic voluntary hyperpnea or hyperventilation, hyperosmolar aerosols, including 4.5% saline, and dry powder mannitol) (4). However, there is less clinical experience with these tests and their external validity for the non-athletic population remains controversial at this point in time (5).

14.2 Instrumentation

Instrumentation includes:

- treadmill or cycle ergometer
- 12 lead printed-copy capacity ECG
- blood pressure cuff and sphygmomanometer
- calibrated spirometer

- metered dose inhaled bronchodilators
- pulse oximeter
- hydrometer
- thermometer
- equipment for measuring ventilation (optional)

Note: Resuscitation equipment is mandatory for an EIB test to be performed

14.3 Technique

14.3.1 Pre-Test Procedures:

- Informed consent should be obtained and witnessed by personnel who can accurately describe the test and potential risks.
- Perform a baseline spirometry. The FEV₁ must be greater than 1.5 L or 70% of predicted in order to proceed.
- Obtain baseline ECG and blood pressure. Leave cuff on the arm in case it is needed.
- Apply nose clips during exercise to ensure mouth breathing to prevent air humidification and warming.
- Approach the target workload (see below) while the patient inspires dry air less than 25°C and, ideally, air humidity below 60 % (< 10 mg H₂O/L). Cold air conditioning is helpful to reach these targets. Another alternative is to make the subject inspire dry air through a mouthpiece and a two-way breathing valve. A dry inhalate is obtained by filling talc-free meteorological balloons (Douglas bag) with gas from a medical-grade compressed air source.

14.3.2 Test Procedures:

The ideal EIB protocol involves a rapid increase in exercise intensity over approximately 2-4 minutes to achieve a high $\dot{V}E$ (6, 7). Once this level of exercise is attained, the subject should continue exercise at that intensity for an additional 4-6 minutes (see **Protocols**).

Sports-specific exercise is probably the most relevant for elite athletes that can be tested during the activity that causes symptoms. This includes inhalation of air at very low temperatures. Although not mandatory, measurement of $\dot{V}E$ allows comparisons to be made over time and between subjects. Although HR is often used as a surrogate measure of the intensity of exercise, it should be noted that the relationship between HR and $\dot{V}E$ varies widely based on fitness and other factors.

Table 7: Useful pre-test calculations and target intensity according to different physiological variables

	Calculations	Target
HR (bpm)	Peak HR= 210-(0.65x age in years)	> 80-90 %
$\dot{V}E$ (L/min)	MVV= FEV ₁ x 35 (or 40) $\dot{V}E$ (L/min)= (28x $\dot{V}O_2$ (L/min)) + 0.27	> 40-60% MVV* or 17.5 – 21 x FEV ₁
$\dot{V}O_2$ (mL/kg/min)	$\dot{V}O_2$ (L/min) = (0.01 x work rate) + 0.5	> 35 ml/min/kg

Obs: *80% in elite athletes. Target settings are adjusted to suit the patient's fitness level.

Note: Low temperature and humidity are critical for EIB

14.3.3 Treadmill protocol

Walking/running has the advantage to elicit a greater $\dot{V}E$ response to exercise compared to bicycle exercise, i.e. the intensity targets are more rapidly achieved with running exercise compared with cycling. However, the target exercise intensity is more difficult to estimate because work rate (W) cannot be calculated varying greatly with weight, stride length, balance, etc. There are nomograms relating $\dot{V}O_2$ /kg to speed and slope of the treadmill but they are frequently inaccurate in practice. Following the general rule, treadmill speed and grade are chosen to produce 4-6 minutes of exercise at near maximum targets with duration of exercise 6-8 minutes. In practice, it is easier (and safer) to quickly reach a high but comfortable speed and readjust grade to "fine tuning" the increase in HR or $\dot{V}E$. For most young, normal-weight and non-athletic subjects, speed greater than 3 mph (about 4.5 km/h) and a gradient greater than 15% or an $\dot{V}O_2$ of 35 ml/min/kg or greater will usually achieve the target $\dot{V}E$ or HR. Following exercise, there should be a brief cool-down phase for 1 to 2 minutes.

14.3.5 Bicycle Ergometer

The main advantage of bicycle exercise is that target work rate can be more accurately estimated once one established the target $\dot{V}E$ and takes into consideration expected $\dot{V}E$ - $\dot{V}O_2$ and $\dot{V}O_2$ -work rate relationships (Table 7).

Working examples for a subject with a baseline FEV₁ of 2.0 L (from Table 7):

- Estimated MVV= FEV₁ x 40 = 2.0 x 40 = 80 L/min
- Target $\dot{V}E$ = MVV x 0.6= 48 L/min
- To elicit the target $\dot{V}O_2 = (\dot{V}E / 28) - 0.27 = 1.71 - 0.27 = 1.44$ L/min
- To reach the target WR = $\dot{V}O_2 - 0.5 / 0.01 \cong 95$ W

and

- Estimated MVV= FEV₁ x 35= 2.0 x 35= 70 L/min
- Target $\dot{V}E$ = MVV x 0.6= 43 L/min
- To elicit the target $\dot{V}O_2 = (\dot{V}E / 28) - 0.27 = 1.53 - 0.27 = 1.26$ L/min
- To reach the target work rate= $(\dot{V}O_2 / 0.01) - 0.5 \cong 125$ W

An equation based on these calculations establishes target work rate (W) as = (53.76 x FEV₁) - 11.07 (6). There are two strategies of achieving the desired exercise level:

1. Rapid increase in the work rate over the first 1 to 2 minutes to the pre-determined work rate, then continue for 6 to 8 minutes.
2. In adults it is recommended for safety reasons that the high-work plateau be approached in three steps to allow for careful observations of the cardiopulmonary response: 2 minutes warm-up at a low intensity, 2 minutes at a moderate work rate, 5 to 8 minutes at the target work rate. Alternatively, the work rate is set at 60% of target in the first minute, 75% for the second minute, 90% for the third and 100% in the fourth (keeping this intensity for 4-6 min)(6).

14.4 Measurements

A 12 lead ECG must be applied. At least 3 leads must be monitored throughout exercise and at least 3 minutes post exercise. FEV₁ is measured pre-exercise and at 5, 10, 15, 20, and 30 minutes post-exercise, but may be recorded more frequently if a severe response is expected. According to both the *1999 ATS/ERS Guidelines for Methacholine and Exercise Challenge Testing* (6) and the *2013 ATS Clinical Practice Guideline on EIB* (7) at least two reproducible FEV₁ manoeuvres should be measured serially at each interval after exercise challenge, with the highest acceptable value recorded. If the FEV₁ has returned from its nadir to the baseline level or greater, spirometry testing may be terminated 20 minutes post-exercise. Without confirming the FEV₁ has reached its nadir, it is not possible to assess the severity of EIB. An FVC manoeuvre is not required, as repeated efforts can be exhausting for the subject.

If the FEV₁ falls by less than 20%, complete all measurements and give the patient a bronchodilator only if FEV₁ has not returned to within 10% of baseline value. If the FEV₁ fall is greater than 20%, give the patient a bronchodilator immediately and continue monitoring FEV₁ until it returns to within 10% of baseline value. Subjective symptoms (e.g., Borg scale) pre, during and post-exercise should be obtained and quantified post exercise.

14.5 Testing Prerequisites

The Medical Director of the laboratory, another physician, or another person appropriately trained to treat acute bronchospasm, including appropriate use of resuscitation equipment, must be physically present to respond quickly to an emergency. Patients should not be left unattended during the procedure once the exercise has begun.

Acceptable and reproducible spirometry is performed and the results known prior to exercise challenge. A resting ECG is performed and the results known to the supervising physician. Check that the patient has refrained from medications as outlined in Chapter 13: Methacholine Challenge Test. The patient should abstain from eating a heavy meal, smoking cigarettes, and consuming alcohol and drinks containing caffeine 3 hours prior to test and should have refrained from exercise for at least 4 hours. As mentioned, this is an important feature because there is a variable period of refractoriness after an episode of EIB. The following conditions are known to reduce the sensitivity of the test and the subject should be specifically asked about:

- use of short-acting and long-term preventative asthma medications
- recent intense or intermittent warm-up exercise
- recent use of non-steroidal anti-inflammatory medication
- recent exposure to inhaled allergens

14.6 Testing Indications

Indications for this test include the need to:

- diagnose asthma as the cause of cough, dyspnea, wheeze or chest tightness, that occurs during or soon after exercise
- objectively confirm a suspected diagnosis of asthma in patients with atypical presentations, or lack of response to conventional therapy

14.7 Testing Contraindications

14.7.1 Absolute Contraindications:

- Severe airflow limitation ($FEV_1 < 50\%$ predicted, or <1.0 L in adults)
- Heart attack or stroke in last 3 months
- Changes in the resting ECG suggesting acute or recent myocardial event
- Unstable cardiac ischemia or malignant arrhythmias
- Severe aortic stenosis or suspected or known aortic aneurysm
- Uncontrolled hypertension, systolic blood pressure >200 mmHg, diastolic blood pressure >100 mmHg

14.7.2 Relative Contraindications:

- Moderate airflow limitation ($FEV_1 < 70\%$ predicted or 1.5 L in adults)
- Inability to perform acceptable-quality spirometry
- Known electrolyte abnormalities
- Uncontrolled diabetes
- Orthopedic or other limitations to exercise
- Current or recent respiratory tract infection

14.8 INDICATIONS FOR STOPPING AN EXERCISE TEST

Cardiac signs and symptoms

- Progressive angina (3 on a 1 - 4 scale)
- Ventricular tachycardia
- >1 mm horizontal or down-sloping ST depression
- A significant drop (>20 mm Hg) in blood pressure or failure of the blood pressure to rise over several minutes of exercise
- Onset of second or third degree heart block
- Exercise-induced left bundle branch block
- Sustained supraventricular tachycardia
- Ventricular couplets or ectopy more than 10 per minute

Other symptoms

- Lightheadedness, confusion, nausea, ataxia, pallor, etc.
- Patient complains of severe chest tightness or wheezing
- Volitional termination by the patient (i.e. cannot continue)

Monitoring

- Failure of the ECG or blood-pressure monitoring system

14.9 Reporting Guidelines

The difference between the pre-exercise FEV₁ value and the lowest FEV₁ value recorded within 30 minutes after exercise is expressed as a percentage of the pre-exercise value. A decrease below 90% of the baseline FEV₁ (i.e., a 10% decrease) is a generally accepted abnormal response, particularly if this is observed at two consecutive time points (6,7). Higher values for % fall in FEV₁ (>15 %) have been recommended for diagnosing EIB in children. Some laboratories use the same higher criterion for adults because of the greater specificity but a > 10 % decrease should be valued according to the pre-test probability (which is usually high in subjects referred to an EIB test) (6,7).

Note: A 10% post-exercise decrease in FEV₁ establishes EIB in a subject with high pre-test probability

Table 8: EIB severity gradation

	Δ (post-pre/pre) FEV ₁
Mild	> 10 % - <25 %
Moderate	≥ 25 - < 50%
Severe	≥ 50 *

Obs: A decline in FEV₁ of >30% in a patient on inhaled steroids would be considered severe (7)

Other outcomes are:

- Type of exercise device
- Target work rate (cycle ergometer)
- Actually performed work rate (cycle ergometer) or speed/grade (treadmill)
- Duration of the testing (min)
- Sustained HR (bpm) and length of time (min) at target HR
- Sustained $\dot{V}E$ (L/min) and length of time (min) at target $\dot{V}E$ - if measured
- Sustained $\dot{V}O_2$ (ml/min/kg or L/min) and length of time (min) at target $\dot{V}O_2$ - if measured
- End-exercise systolic/diastolic blood pressure
- End-exercise SpO₂ (%) and nadir
- ECG reporting and any abnormalities

14.10 Quality Control

Treadmill or bicycle need not be calibrated as actual workload and grade are not relevant as long as the target heart rate is achieved and maintained. The spirometer should be calibrated according to Chapter 6. The respiratory circuit is checked weekly for leaks if inspired dry air is used.

Special care should be taken that exercise must be avoided for at least four hours before testing as prior exercise has been found to exert a protective effect on the airways. When treatment efficacy is being monitored, some medications may be continued as directed by the requisitioning physician. These medications must be noted on the report.

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Chapter 15 Cardiopulmonary Exercise Test (Stage 1)

List of main abbreviations

AT: anaerobic threshold	RER: respiratory exchange ratio
b-b-b: breath-by-breath	RCP: respiratory compensation point
COPD: chronic obstructive pulmonary disease	Ti: inspiratory time
CPET: cardiopulmonary exercise testing	TE: expiratory time
ECG: electrocardiogram	TTOT: total respiratory time
f : respiratory rate	Ti/TTOT: duty cycle
HR: heart rate	$\dot{V}CO_2$: carbon dioxide output
IC: inspiratory capacity	$\dot{V}E$: minute ventilation
ILD: interstitial lung disease	$\dot{V}E / \dot{V}CO_2$: ventilatory equivalent for CO_2
LLN: lower limit of normality	$\dot{V}E / \dot{V}O_2$: ventilatory equivalent for O_2
MVV: maximal voluntary ventilation	$\dot{V}O_2$: oxygen uptake
PETCO ₂ : end-tidal partial pressure for CO_2	$\dot{V}O_2/HR$: oxygen pulse
PETO ₂ : end-tidal partial pressure for O_2	VT: tidal volume

15.1 Overview

Exercise intolerance, usually due to disabling breathlessness is the main symptom of patients with chronic respiratory diseases. Symptomatic limitation of exercise tolerance depends on the integration of the main body systems, including the subjective response to stress.

Cardiopulmonary exercise testing (CPET) attempts to objectively quantify the impairment in exercise tolerance and identify the limiting mechanisms (respiratory-mechanical, pulmonary vascular/gas exchange, cardiovascular, muscular) that accompany many pulmonary disorders (1-5). The procedure involves the measurements and recording of metabolic, ventilatory, gas-exchange, cardiovascular and subjective responses to incremental work rate tests on a cycle ergometer or treadmill. More commonly, these physiological responses are directed to proprietary software with technological capabilities of displaying the recorded data in numerical and graphical formats. In most clinical scenarios (e.g. detection of mechanisms of exercise impairment), spirometry needs to have been performed prior to testing with results available. Resting ECG is also needed prior to testing unless young healthy individuals are evaluated.

15.2 Instrumentation

Instrumentation used includes a:

- Calibrated cycle ergometer or treadmill
- Two or three lead ECG for continuous monitoring, with 12 lead capacity
- Nose clip-mouthpiece or masks
- Respiratory valves and tubing in some systems
- Flow sensing device (e.g., turbine, pneumotach, Pitot tube, mass flow sensor) for measuring ventilation.
- Breath-by-breath (“b-b-b”) technology or mixing chamber to measure expired gas concentrations and relate them to ventilatory measurements
- Blood pressure cuff and sphygmomanometer
- Pulse oximeter
- Computerized system for continuous data acquisition, display and printing of results

- Effort exercise scale such as the modified Borg Scale

Note: Resuscitation equipment is mandatory. The equipment needs to include a defibrillator, ambubag with mask and oxygen. Time to defibrillation and EMS response time are most important variables in survival from a potentially lethal cardiac arrhythmia.

15.3 Techniques

A basic standard protocol for CPET using a cycle ergometer is widely accepted and is briefly described. ECG electrodes, blood pressure cuff, nose clip-mouthpiece or mask, and the necessary devices for $\dot{V}E$ and metabolic measurements are attached to the patient. The test should be carefully explained to the subject, including the meaning of the Borg scale. It is crucial to “anchor” the scale to 10, i.e., the maximum ever felt. Resting measurements are taken. The workload is increased by equal increments every minute or continuously during the test (“ramp” protocol). Variables are measured and recorded continuously (“b-b-b” systems) or each 15-20 s (mixing chamber). The patient is asked to rate his/her breathlessness and leg effort every minute. If technically available, inspiratory capacity (IC) manoeuvres can be performed serially to track exercise-induced dynamic hyperinflation (assuming a constant total lung capacity). The test is continued until the patient is symptom-limited or until the attending physician stops the test. In the first case, the patient is asked to report which symptom(s) made he/she stop exercising. Presence of chest pain or neurological symptoms should always be inquired.

Note: The Borg scale is the preferred method of rating symptom limitation which rates breathlessness and leg effort from 0 (no symptoms) to 10 (maximal symptoms).

15.4 Measurements

Some commercially-available systems for cardiopulmonary exercise testing do not allow all of the measurements listed below to be performed. Key measurements are in bold.

Metabolic

- $\dot{V}O_2$ (L/min): oxygen uptake, rate of O_2 transfer from alveoli to capillary blood
- $\dot{V}CO_2$ (L/min): carbon dioxide output, rate of CO_2 wash-out from capillary blood to alveoli
- **RER**: respiratory exchange ratio ($\dot{V}CO_2 / \dot{V}O_2$)

Ventilatory

- $\dot{V}E$ (L/min): minute ventilation, total pulmonary ventilation
- **V_T** (L): tidal volume, air volume displaced in a single breath
- **f** (rpm): respiratory rate, frequency of respiratory movements
- **T_I** (s): inspiratory time, time elapsed from the start to the end of inspiration
- **T_E** (s): expiratory time, time elapsed from the start to the end of expiration
- **$TTOT$** (s): total respiratory time, time elapsed from the start of inspiration to the end of expiration

- **TI/TTOT**: duty cycle, time spent on inspiration relative to total respiratory time
- $\dot{V}E / \dot{V}O_2$: ventilatory equivalents for O₂, liters of ventilation needed to uptake 1 liter of O₂
- $\dot{V}E / \dot{V}CO_2$: ventilatory equivalents for CO₂, liters of ventilation needed to wash-out 1 liter of CO₂
- **IC (L)**: inspiratory capacity, volume available for inspiration
- **EELV (L)**: end-expiratory lung volume, volume at the end of a relaxed expiration (total lung capacity – IC)

Gas exchange

- **PETO₂ (mmHg)**: end-tidal partial pressure for O₂, partial O₂ tension at the end of expiration (i.e., after breathing circuit/dead space air has been expired)
- **PETCO₂ (mmHg)**: end-tidal partial pressure for CO₂, partial CO₂ tension at the end of expiration (i.e., after breathing circuit/dead space air has been expired)
- **SpO₂ (%)**: oxygen saturation by pulse oximetry

Cardiovascular

- **HR (bpm)**: heart rate, frequency of heart beats
- $\dot{V}O_2/HR$ (mL/min/beat): oxygen pulse, amount of O₂ uptaken per beat
- **SBP (mmHg)**: systolic blood pressure
- **DBP (mmHg)**: diastolic blood pressure

Subjective

- **Dyspnea** (Borg units)
- **Leg effort** (Borg units)

15.5 Quality Control

Many of the current exercise systems integrate devices measuring $\dot{V}E$, expired gases, saturation, ECG with either the exercise bicycle or treadmill with a computerized system. As such the test procedures and calibration methodology are usually governed by proprietary algorithms. Nevertheless, minimal calibration requirements apply (**Table 9**).

Table 9: Calibration requirements

EQUIPMENT	RANGE (%)	ACCURACY* (%)	REPRODUCIBILITY	FREQUENCY RESPONSE (ms)	TEST SIGNAL
O ₂ analyzer	0-100	1	1%	<130	Minimal 2-point cal
CO ₂ analyzer	0-10	1	1%	<130	Minimal 2-point cal
Flow meter	0-14 L/s	3	3%	<40	3 L syringe
Cycle Ergometer	0-400 W	2% or 3W above 25W			Dynamic torque meter
Treadmill	0-10 mph 0-20% grade	0.2 mph 0.5%			Timed rev of marker on belt Measure with carpenter's ruler

* Linearity within the indicated percentage of full scale for each apparatus.

The system must be calibrated daily or prior to testing and includes calibration of the air flow or volume transducer and two point calibration of each gas analyzer with two precision-analyzed gas mixtures (e.g., 5% CO₂ & 12% O₂; 0% CO₂ & 21% O₂). In systems utilizing “b-b-b” gas exchange measurements the delay time between solenoid activation and detection of change in gas analyzer output should also be measured daily. Less frequent calibrations include blood pressure transducers, exercise bicycle or treadmill. The respiratory circuit in closed systems is checked weekly for leaks.

With mechanical bicycles several workloads are tested using known weights for accuracy yearly. Pedaling frequency is monitored carefully. Electronic bicycles are calibrated yearly with a physical balance such as a torque calibrator. The belt velocity and treadmill grade are tested yearly. For more specific calibration techniques, follow the manufacturer’s recommendations.

Reproducibility may be assessed with biological controls using one or two healthy laboratory personnel. Although the ATS document recommends at least monthly tests, this may not be practical and instead quarterly biological testing is recommended. Care must be taken to conduct this test on the same time of the day, as there may be significant diurnal variation and to use an identical protocol. A basic approach to quality control using the biological controls and a cycle ergometer includes:

- 3 constant load work rates (e.g. 50 W, 75 W and 100 W) for 6 min each (steady-state). If one or more of these work rates is above the “anaerobic threshold” (AT), select lower loads
- Record last minute $\dot{V}O_2$, $\dot{V}CO_2$ and $\dot{V}E$
- Expect $\dot{V}O_2$ (mL/min)= 10 x (work rate in W) + 500 ml (± 100 ml)
- Expect $R \leq 1$
- $\dot{V}E / \dot{V}O_2$ and $\dot{V}E / \dot{V}CO_2 < 28$ (in young subjects)

15.6 Testing Prerequisites

Spirometry (to estimate MVV and, therefore, the maximal ventilatory capacity) should be properly performed and the results known prior to testing. Some commercially-available systems allow continuous comparison between the maximal flow-volume loop at rest and the tidal flow-volume loops during exercise thereby estimating expiratory flow limitation. If this technique is to be used, care should be taken to obtain a technically-adequate expiratory limb. The clinical question(s) behind the test requisition should be clearly known. A resting electrocardiogram was performed and the results known to the supervising physician except for young, otherwise healthy, individuals.

15.7 Testing Indications

Indications for this test include the need to:

- objectively assess symptoms (especially dyspnea) that limit exercise performance
- detect early disease of the cardiopulmonary system (e.g., interstitial lung disease) that may limit exercise performance
- identify the contribution of multiple factors (cardiac reserve, pulmonary reserve, neuromuscular function, etc.) to poor exercise performance
- establish the prognosis in chronic pulmonary diseases (COPD, ILD)
- detect exercise-related O₂ desaturation
- assess and quantify impairment and/or occupational disability
- assist in predicting post-operative pulmonary function prior to lung resection

15.8 Contraindications and Safety

The contraindications for performing the exercise test include those below. This list, however, should not replace good clinical judgement.

15.8.1 Absolute contraindications

- Recent complicated myocardial infarction(3-5 days)
- Changes in the resting ECG that suggest an acute or recent myocardial event
- Unstable angina
- Uncontrolled cardiac arrhythmias
- Severe valve stenosis and known or suspected dissecting aortic aneurysm
- Active or suspected acute pericarditis, endocarditis or myocarditis
- Acute congestive heart failure
- Acute febrile illness
- Acute asthma
- Recent systemic or pulmonary embolus
- Significant emotional distress (psychosis)
- SpO₂ < 85% or respiratory failure

Note: The physician must be in attendance during the CPET.

15.8.2 Relative Contraindications

- Systemic hypertension. Resting SBP >200 mmHg, DBP >120 mmHg
- Resting tachycardia (HR >120 bpm)
- Frequent ventricular or atrial ectopy
- Hypertrophic cardiomyopathy
- moderate valvular heart disease
- Known electrolyte abnormalities (e.g., hypokalemia and hypomagnesemia)
- Uncontrolled diabetes or electrolyte abnormalities
- Orthopedic limitations to exercise
- Neuromuscular, musculoskeletal or rheumatoid diseases that are exacerbated by exercise
- Advanced or complicated pregnancy
- Cardiomyopathy

Monitored exercise testing is considered relatively safe with a reported complication rate of 0.5 to 1.0 in 10,000 tests.

15.9 Criteria for immediately stopping the exercise test:

In the vast majority of exercise tests, patients should be verbally encouraged before and during the test, to give a maximal effort with the goal of achieving physiologic limitation. Exceeding a preset HR criterion should not be used as a criterion for stopping exercise. The most accepted criteria for exercise termination before symptom limitation are:

- Chest pain suggestive of ischemia
- Ischemic ECG changes which is taken as >1mm ST segment depression for >80ms with downsloping more specific than horizontal or upsloping
- J point elevation for 3 consecutive beats for 60ms after the J point
- Complex ectopy
- Second or third degree heart block (high degree av block)
- Fall in SBP >20 mmHg from the highest value during exercise
- Hypertension (SBP >250 mmHg systolic; DBP >120 mmHg)
- Severe desaturation: SpO₂ ≤ 80% when accompanied by symptoms and signs of severe hypoxemia
- Sudden pallor
- Loss of coordination
- Mental confusion
- Dizziness or faintness
- Signs of respiratory failure

In situations in which the exercise is terminated because of the above criteria, the patient should be observed until the patient is stable and physiologic variables have returned to baseline conditions.

15.10 Reporting Guidelines

The reports sent out to the referring physician should contain not only key summarizing data but also some representative graphs that are in a format that can be reviewed and compared with repeat testing (**Tables 10 and 11**). The narrative summary should be understandable and comprehensive to include the guideline recommendations below.

The report includes:

- Patient demographics
- Reason for the test
- Type of test, device and protocol
- Pre-test clinical and resting physiological responses (if known)
- Concise evaluation of main metabolic, ventilatory, cardiovascular, gas exchange and subjective responses, including if there is or not subjective/objective evidence of maximum effort.
- Description of symptoms reported by the patient (Borg scale score) at rest, and periodically during the test and at test termination. Symptoms for both leg effort and breathlessness need to be reported
- Presence or absence of changes in blood pressure or heart rate or rhythm and any ECG changes suspicious for ischemia
- Final impressions, suggesting the etiology of exercise limitation/reason why the test was terminated
- Recommendations in line with the underlying clinical question

The final report should incorporate the findings of the study in a summary that is understandable and consistent with the data obtained. Any deviation from the expected should be discussed and explained if possible. An exercise prescription based on the results of the study may be suggested and further testing if required can be recommended. The record should contain the raw (tabular) data and graphics that are pertinent to a clinical analysis of the test (**Tables 10 and 11**). Special care should be taken in relation to data averaging in modern “b-b-b” systems. It is recommended that tabular data are mean of 20-30 s and graphic data points are average of 8 breaths or 10 s.

Note: Report should contain key data in both numerical and graphical formats.

Table 10: Suggested display summarizing data derived from an incremental cardiopulmonary exercise test. AT is the “anaerobic threshold”.

	REST	AT		PEAK		
		Actual	% Peak	Actual	Pred	% Pred
Time (min)						
Work rate (W)						
Metabolic $\dot{V}O_2$ (L/min) $\dot{V}CO_2$ (L/min) RER						
Ventilatory $\dot{V}E$ (L/min) VT (L) f (rpm) $\dot{V}E/\dot{V}O_2$ $\dot{V}E/\dot{V}CO_2$						
Gas exchange P _{ET} O ₂ (mmHg) P _{ET} CO ₂ (mmHg) SpO ₂ (%)						
Cardiovascular HR (bpm) $\dot{V}O_2$ /HR (mL/min/beat) SBP (mmHg) DBP (mmHg)						
Subjective Dyspnea Leg effort						

Table 11: Suggested graphs to show the dynamic responses to incremental cardiopulmonary exercise test. AT is the “anaerobic threshold” and RCP is the “respiratory compensation point”.

Dependent Variables (y-axis)	Independent variable (x-axis)	Physiological Information
$\dot{V}O_2$ (L/min)	Work rate (W)	<ul style="list-style-type: none"> • Estimation of aerobic “efficiency” • Assessment of changes in linearity
$\dot{V}CO_2$ (L/min)	$\dot{V}O_2$ (L/min)	<ul style="list-style-type: none"> • “V-slope” estimation of AT
RER	$\dot{V}O_2$ (L/min)	<ul style="list-style-type: none"> • Assessment of hyperventilation
$\dot{V}E / \dot{V}O_2$ $\dot{V}E / \dot{V}CO_2$	$\dot{V}O_2$ (L/min)	<ul style="list-style-type: none"> • Estimation of AT: ventilatory method • Assessment of ventilatory “efficiency”
PET O_2 (mmHg) PET CO_2 (mmHg)	$\dot{V}O_2$ (L/min)	<ul style="list-style-type: none"> • Confirmatory of AT: ventilatory method • Dynamic changes in PETCO_2, an index of gas exchange efficiency or hyperventilation
$\dot{V}CO_2$ (L/min)	$\dot{V}E$ (L/min)	<ul style="list-style-type: none"> • Assessment of ventilatory “efficiency” • Identification of the RCP
VT (L) f (rpm)	$\dot{V}E$ (L/min)	<ul style="list-style-type: none"> • Breathing pattern analysis
Sp O_2 (%)	$\dot{V}O_2$ (L/min)	<ul style="list-style-type: none"> • Assessment of exercise oxygenation
HR (bpm) $\dot{V}O_2$ /HR	$\dot{V}O_2$ (L/min)	<ul style="list-style-type: none"> • Cardiovascular evaluation • Assessment of changes in linearity/“plateau” in O_2 pulse
Leg effort Dyspnea	$\dot{V}O_2$ (L/min) $\dot{V}E$ (L/min)	<ul style="list-style-type: none"> • Perceptual assessment to increased metabolic demands

15.11 Useful Interpretative Data

Table 12: Key variables and cut-offs for clinical interpretation of incremental cardiopulmonary exercise testing by the Respiriologist

Time (min)	<ul style="list-style-type: none"> • Ideal duration of the incremental phase: 8-12 min
Work rate (W)	<ul style="list-style-type: none"> • Can only be calculated in cycle ergometer exercise • Peak WR is protocol dependent
Metabolic Responses	<ul style="list-style-type: none"> • $\dot{V}O_2$ peak LLN: < 83% predicted • $\dot{V}O_2$ peak <83%–≥70 (mild impairment); 69-50 moderate impairment; < 50% (severe impairment) • $\Delta\dot{V}O_2 / \Delta$ work rate \cong 10 mL/min/W • Peak RER is protocol dependent. Low RER (< 1.1) should <u>not</u> be viewed as evidence of sub-effort in symptomatic patients • Ventilatory (“anaerobic” threshold) is 40-60% <u>predicted</u> $\dot{V}O_2$ peak in normal and higher in athletes.
Ventilatory Responses	<ul style="list-style-type: none"> • <u>Estimated</u> MVV ($FEV_1 \times 37.5$) is preferred to measured MVV (overestimation in ILD and underestimation in COPD) • Peak $\dot{V}E/MVV$ < 0.7 to 0.8. Higher values indicate reduced ventilatory reserve. • $\dot{V}E - \dot{V}CO_2$ relationship (as a ratio at the AT or as a slope through the linear phase) estimates “ventilatory efficiency” to metabolic demand • Peak f usually < 50 rpm. Increased in ILD. • Peak V_T is usually 60% vital capacity. • Decrease in adequately performed IC > 200 mL from rest suggests dynamic hyperinflation (e.g., COPD)
Gas exchange Responses	<ul style="list-style-type: none"> • Decreases > 4% indicate exercise-induced O_2 desaturation • $PETCO_2$ increases from rest to the AT. Reduced values indicate gas exchange inefficiency or hyperventilation.
Cardiovascular Responses	<ul style="list-style-type: none"> • Steep $\Delta HR/\Delta\dot{V}O_2$ relationship and/or reduced peak O_2 pulse indicate decreased stroke volume and/or arterial-venous O_2 difference • Early “plateau” or decrease in O_2 pulse is indicative of impaired stroke volume response to exercise • SBP rise less than 30mm Hg or drop is abnormal • 1mm ST depression for 80 ms downsloping more significant than upsloping or horizontal. 1mm J point elevation for 3 consecutive beats for 60ms is abnormal
Subjective Responses Dyspnea Leg effort	<ul style="list-style-type: none"> • Leg effort is the main limiting symptom in healthy subjects, particularly when cycle ergometry is used

The above are meant for correlative educational purposes. They are to be used as estimates only and are helpful in assessing whether abnormal values may be measurement error from equipment linearity drift or whether it represents physiologic abnormality.

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Chapter 16 Maximal Inspiratory Pressure and Maximal Expiratory Pressure

List of main abbreviations

MEP- Maximal Expiratory Pressure
MIP – Maximal Inspiratory Pressure

16.1 Overview

Maximal Inspiratory and Expiratory Pressures (MIP/MEP) measure the strength of the respiratory muscles. The MIP measures the strength of inspiratory muscles (external intercostal, sternocleidomastoid, diaphragm) whereas the MEP measures the strength of expiratory muscle (internal intercostal and abdominal muscles). It is a common practice that MEP is measured at total lung capacity (TLC) and MIP is measured at residual volume (RV).

These tests are very effort-dependent and the patient must be well motivated in order to obtain the optimal results.

16.2 Pre-requisites

Spirometry

16.3 Indications

These tests are normally used to identify muscle weakness or inefficiency as a cause of dyspnea or hypoventilation and should not be routinely performed otherwise.

Indications for this test include the need to:

- identify respiratory muscle weakness as a cause for unexplained dyspnea,
- hypoventilation or non-parenchymal lung restriction with reduced peak flow or vital capacity
- assess and quantify the respiratory muscle weakness for patients with known neuromuscular diseases (e.g. Guillain-Barré syndrome, myasthenia gravis, polymyositis and amyotrophic lateral sclerosis) or chest deformities (e.g. scoliosis)

16.4 Contra-indications

MIP/MEP manoeuvres should be performed with caution in the following circumstances:

- recent myocardial infarction (within 4 weeks) or myocarditis
- unstable angina/chest wall pain
- uncontrolled systemic hypertension
- recent pneumothorax
- lung biopsy within previous week

- significant ongoing hemoptysis
- recent eye, abdominal, or spinal surgery

16.5 Indications for Test Termination

- Syncope
- Angina
- Dizziness/headache/muscle cramping not relieved by rest
- Mental confusion
- Patient requests to stop

16.6 Instrumentation

The equipment can be as simple as a portable strain gauge or electronic handheld pressure manometer. Most new pulmonary function systems incorporate these tests with simple lung volume level indication to TLC or RV.

A typical portable handheld unit consists of a three-way valve with a 2.5 cm internal diameter.

One outlet is open to room air, the other outlet is sealed with a rubber stopper and contains a small hole of 1.0- 2.0 mm inside diameter as a “controlled leak” and 15 mm in length. The purpose of a small hole during the measurement of MIP is to prevent glottic closure as well as facial muscles from generating artificial higher pressure.

A rubber mouthpiece and nose clip.

16.7 Techniques and Measurements

Patients should sustain maximum pressure for at least one second. Although either peak or sustained one second pressure can be measured, the Task Force is biased to the measurement of sustained one second pressures as predictive values are based on sustained one second pressure measurements.

- Place a tight-fitting rubber mouthpiece onto the mouthpiece adapter.
- Explain the procedure to the patient; ensure that there is no contraindication for the test.
- Instruct the patient to keep a tight lip seal and to give maximum effort.

16.7.1 Maximal Inspiratory Pressure

- Ensure that the patient is in the upright sitting position and the “controlled leak” is properly in place.
- Place the mouthpiece properly in the patient’s mouth and apply a nose clip.
- Instruct the patient to breathe out all the way slowly, and remind the patient to keep the lips tight around the mouthpiece.
- When the patient is at residual volume, close shutter and instruct the patient to immediately breathe in as hard as possible for at least 1 second.

- A minimum of 3 and a maximum of 8 measurements must be obtained.
- If the final effort is the highest value, instruct the patient to perform one more measurement.
- The test is said to be reproducible when the highest two values are within 10%.
- Depending on the patient, allow the patient to rest for 30 to 60 seconds between tests.

16.7.2 Maximal Expiratory Pressure

- Ensure that the patient is in the upright sitting position (the “controlled leak” needs not to be removed as it will not change the lung volumes significantly).
- Place the mouthpiece properly in the patient’s mouth and apply a nose clip.
- Instruct the patient to apply hands to cheeks.
- Instruct the patient to breathe in all the way slowly, and remind the patient to keep the lips tight around the mouthpiece.
- As soon as the patient cannot breathe in anymore (at TLC level), instruct the patient to immediately push out as hard as possible for at least 1 second.
- A minimum of 3 and a maximum of 8 measurements must be obtained. If the final effort is the highest value, instruct the patient to perform one more measurement.
- The test is said to be reproducible when the highest two values are within 10%.
- Depending on the patient, allow the patient to rest for 30 to 60 seconds between tests.

16.8 Data Analysis/Calculations

If a recorder is used, measure the centimeter deflection of the pressure reading and convert to a pressure reading (usually 1 cm deflection = 10 cm H₂O). Measure and record all values sustained for at least 1 second. Report the highest most reproducible, sustained MIP and MEP that meet the acceptability criteria. Results are reported in cm H₂O and compared to predicted values that are based on the same lung volumes as the observed values. If a strain gauge or manometer is used, the only measurement that can be recorded is peak pressure.

16.9 Reporting Guidelines

The report includes:

- results of baseline spirometry
- comments on patient’s condition
- technical comments on patient effort
- comparison of patient measurement to predicted normal values
- comments on the significance and relevance of the results to the patient’s pathophysiology

16.10 Quality Control

Check the calibration of the measurement system with water/mercury manometer or traceable electronic digital pressure monitor each day of use. Ensure that the measurement system reads “zero” at ambient pressure. Using a specialized syringe, apply 100 cm H₂O from the manometer for both negative and positive pressures. The measured reading should be within 5% of the expected value. Adjust the measured reading appropriately to the system or a recorder if required.

Pressure transducers must be calibrated quarterly over the range of use ± 200 cm H₂O. To accurately interpret the results, poor patient cooperation must be distinguished from actual muscle weakness.

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Chapter 17 Arterial Blood Sampling, Blood Gas Analysis and Hemoximetry

17.1 Overview

Arterial blood is usually drawn anaerobically from the radial artery via a single percutaneous needle puncture. Alternatively, an arterialized capillary blood sample can be collected by pricking the finger or ear lobe. Either method provides a specimen for blood gas analysis and hemoximetry.

The analysis of arterial blood provides information on the oxygenation, ventilatory, and acid-base status in evaluating respiratory function; arterialized venous blood provides an estimate of arterial values. The values directly measured from the arterial or arterialized blood are the carbon dioxide tension (PCO_2), oxygen tension (PO_2) and the hydrogen ion concentration (pH). Other derived or calculated values that are clinically useful are the plasma bicarbonate (HCO_3^-), base excess/deficit, and oxygen saturation (calculated SO_2). The usual values measured in hemoximetry (i.e., Co-oximetry) are the concentration of total hemoglobin (tHb), oxyhemoglobin (O_2Hb), carboxyhemoglobin (COHb), methemoglobin (MetHb), and oxygen saturation of tHb (measured SO_2)

17.2 Pre-Requisites

Written or verbal informed consent is obtained from the patient.

17.3 Indications

Arterial blood gas analysis is indicated to accurately determine:

Arterial Oxygen tension as in:

- determination of eligibility for home oxygen prescription
- assessment of risk of hypoxemia when flying at altitude
- assessment of hemoglobinopathy
- evaluation of causes of low readings for oxygen saturation by pulse oximetry
- calculation of the alveolar-arterial oxygen gradient

Carbon Dioxide tension as in:

- hypoventilation states
- before initiation of assisted ventilation
- after initiation of assisted ventilation to assess for efficacy and benefit

Acid-Base Status as in:

- evaluation of acidosis or alkalosis

17.4 Contra-indications

Negative Allen test for radial arterial sampling only.

17.5 Relative Contra-indications

Sampling of arterial blood should be undertaken with caution in any patient with a bleeding tendency or who is receiving medications that reduce coagulation.

17.6 Indications for Test Termination

The effort to obtain arterial blood for gas analysis should be terminated when it is not feasible to obtain a sample. In this situation a sample of arterialized capillary blood could be obtained by pricking a finger or ear lobe of arterial blood

17.7 Instrumentation

The instrumentation for arterial blood sampling, blood gas analysis and hemoximetry are as follows:

- An automated blood gas analyzer system consisting of:
 - a pH electrode (Sanz electrode) and reference electrode for measuring the pH
 - a PCO₂ electrode (Severinghaus electrode) for measuring the PaCO₂
 - a PO₂ electrode (Clarke electrode) for measuring the PaO₂
 - a fixed multiple wavelength spectrophotometer (co-oximeter) for measuring tHB, O₂Hb, COHb
 - calibrating gas mixtures and solutions for pH, PCO₂, and PaO₂
 - reagents (rinse, salt-bridge, cleaning solutions) and accessories (electrode membranes, thermal paper, pump tubing)
- three levels (i.e., normal, acidosis, alkalosis) of commercially prepared (aqueous buffer or fluorocarbon-based) quality control material
- personal protective equipment (gloves, outerwear, eyewear)
- preheparinized syringes with a 22 to 25 gauge needles or capillary tubes, engineered sharps (i.e., lancets), antiseptic solution, sterile gauze pads, puncture resistant sharps container
- instrument's operator manual

17.8 Techniques and Measurements

If clinically acceptable the supplemental oxygen should be discontinued for a minimum of 5 minutes prior to arterial puncture. Patients with severe airflow limitation may take longer to equilibrate to the inspired oxygen concentration. Up to 20 minutes may need to elapse before testing is performed. Continuous oxygen saturation monitoring by oximeter should be performed while the patient is off oxygen.

Perform a modified Allen test to assess the adequacy of collateral circulation through the ulnar artery. The modified Allen test must be positive (i.e., good ulnar blood flow) to proceed with the radial puncture. Wipe the puncture site with alcohol and place the patient's hand into a relaxed supine position. Support the patient's hand with a rolled towel while hyper-extending the patient's wrist to approximately 45° from horizontal. Palpate the radial artery to locate a maximal pulse point (MPP) by pressing your index and middle finger on the artery. Slowly advance the needle with the bevel facing upward to pierce the skin at approximately a 45° angle toward the MPP until the blood begins to fill the heparinized syringe. If the artery is missed, slowly withdraw the needle to almost the skin surface then redirect the needle. Withdraw it after an adequate amount of blood (about 1 mL) is obtained and immediately compress the puncture site using a sterile gauge for approximately five minutes (longer time is necessary for patients with bleeding disorders or on anticoagulant therapy). Cap the needle using a one-handed technique and prepare the blood specimen (e.g., expel any air bubbles from the sample) for immediate analysis.

In the case of a negative Allen test and for younger patients, blood can be taken from the finger or ear lobe. Warm up the selected puncture site and wipe it with alcohol. Prick the site with a lancet and allow the free forming blood droplet to fill a capillary tube. After collection, apply firm pressure to the puncture site with a sterile gauge and prepare the sample for immediate analysis.

If the blood is not immediately analyzed it should be stored in ice.

Follow the manufacturer's instructions for injecting or aspirating the specimen into the blood gas analyzer.

17.9 Data Analysis/Calculations

All measured and calculated values are reported from the blood gas analyzer printout. Refer to the instrument's reference manual for all the equations used.

17.10 Reporting Guidelines

Need to specify source of blood sample: either arterial blood or arterialized capillary blood

Need to specify whether blood sample obtained via room air or supplemental oxygen

Younger patients >96%

Older patients >94%

17.11 Quality Control

Most blood gas analyzers automatically calibrate the electrodes and spectrophotometer to determine the status (zero point), sensitivity (comparison between actual and theoretical electrode readings), and drift (stability between calibrations). Follow the manufacturer's recommended time schedule for calibration. In general, a one-point calibration is performed every 30 minutes or before each patient sample. A two-point calibration is performed at least every eight hours and after any corrective maintenance to the electrode.

pH electrode

A one-point calibration is performed using calibrating solution with normal pH (e.g., 7.40) to determine the status of the electrode. A two-point calibration is performed every 8 hours using two pH buffer

solutions (e.g., 7.40 and 6.80) to determine the sensitivity of the electrode. The drift is obtained during the one- and two-point calibrations to determine the electrode performance.

PCO₂ electrode

A one-point calibration is performed using a precision CO₂ gas mixture (e.g., 5.00 %) to determine the status of the electrode. A two-point calibration is performed using two precise mixtures of CO₂ gas concentrations (e.g., 5.00 % and 10.00 %) to determine the sensitivity of the electrode. The drift is obtained during the one- and two-point calibrations to determine the electrode performance.

PO₂ electrode

A zero point value is performed using 0 % O₂ (i.e., 100% pure CO₂). A one-point calibration is performed using one O₂ gas concentration (e.g., 20.00 %) to determine the sensitivity and the drift is calculated.

Co-oximeter

The spectrophotometer is calibrated over all the fixed wavelengths using a water sample (i.e., calibrating solution) to determine the zero point status and drift. A tHb calibration is recommended every three months using a tHb calibrating solution to obtain a calibration factor.

At least two levels of quality control (QC) material must be analyzed every eight hours during which the instrument is used for patient sample analysis. The acceptable QC data range (mean \pm 2 standard deviation from the mean) provided by the manufacturer may be used. The laboratory may also establish their own acceptable ranges by running 20 samples for each level of QC materials with specific lot numbers to be used. In order to avoid defining ranges for a new lot number, ensure there is an adequate supply of the levels of selected lot numbers for the ensuing period of QC testing (e.g., one year).

Independent Health Facilities: Clinical Practice Parameters and Facility Standards

Pulmonary Function Studies

Volume 3 Spirometry & Flow Volume Loop

Chapter 18 Facility Standards for Spirometry and Flow Volume Loop

18.1 Staffing

18.1.1 Medical Staff Qualifications

Medical staff have a certificate of registration for independent practice in Ontario and

- hold a specialty qualification from the Royal College of Physicians and Surgeons of Ontario (or equivalent) in Respiriology,
or
- hold another specialty qualification from the Royal College of Physicians and Surgeons of Canada (or equivalent) and have a minimum of three months prior training and experience on the respiratory disease services of a university-affiliated teaching hospital, such training including experience in the execution and interpretation of pulmonary function tests,
or
- in lieu of the above, have a minimum of six months prior clinical experience in the execution and interpretation of pulmonary function testing. Documentation must be available in the Independent Health Facility

18.1.2 Technologist Qualifications

Technologists performing these tests are:

- a registered cardiopulmonary technologist (RCPT(P))
or
- a registered respiratory therapist (RRT)
or
- another health care professional whose formal training included studies in the anatomy and physiology of the cardiorespiratory system and whose subsequent experience included one month of training in the performance and quality control of spirometry and flow volume loop testing

Note: All technologists must be currently certified in Basic Cardiac Life Support (BCLS)

18.2 Overview

Spirometry and flow volume curves are non-invasive techniques for the measurement of vital capacity, forced expired volume in one second and rates of airflow at various lung volumes. Measurement of the forced vital capacity and corresponding flow rates is the most commonly used test to detect the presence of lung disease and to monitor changes in severity and response to treatment.

Spirometric terms and measurements

Term	Name	Description
FEF _{x%}	Forced expiratory flow x%	The forced expiratory flow when x% of the FVC has been exhaled; FEF _{25%} , FEF _{50%} , and FEF _{75%} are commonly reported.
FEF _{25-75%}	Forced mid-expiratory flow	The average flow over the middle 50% of a FVC manoeuvre.
FET	Forced expiratory time	The time required for the FVC to be expired.
FEV _t	Forced expiratory volume at time (t)	The maximal volume of air exhaled with maximally forced effort in t seconds; 1 and 6 seconds are the most common.
FEV ₁ /FVC	Forced expiratory volume in t seconds to forced vital capacity ratio	The ratio of FEV _t to FVC expressed as a percentage (FEV ₁ /FVC is the most commonly used ratio)
FVC	Forced vital capacity	The maximal volume of air exhaled with maximally forced effort from a point of maximal inspiration.
IVC	Inspiratory vital capacity	The maximal volume of air inhaled slowly from the point of maximal exhalation achieved by a slow expiration from end-tidal inspiration.
MVV	Maximum voluntary ventilation	The maximum volume of air one can ventilate over a specified period of time (e.g., 12 seconds).
PEF	Peak expiratory flow	The maximal expiratory flow generated during an FVC manoeuvre.
SVC	Slow vital capacity	The maximal volume of air exhaled slowly from the point of maximal inhalation.
VC	Vital capacity	The volume change between the position of full inspiration and complete expiration.

Note: Both PEF and MVV are very effort-dependent requiring substantial cooperation and understanding by the patient.

18.2.1 Instrumentation

The following instrumentation is required to perform spirometry and flow volume loop curves:

- A calibrated spirometer linear from 0.5 to 8 L BTPS and accurate to 3% of the reading or 50 mL, whichever is greater when air is put into the system at flow rates from 0-14 litres/sec. The 8 litre volume applies to recently manufactured instruments.
 - those instruments manufactured prior to 1995 with a 7 litre range may still be used
 - the spirometer is able to accumulate volume for at least 15 seconds for FVC and for at least 30 seconds for SVC. If FEV₁ is being measured, the volume criteria is the same as for the FVC and the resistance to airflow is less than 1.5 cm H₂O/litre/sec at flow rates from 0-14 litres/sec
 - the frequency response of the spirometer is flat to 4 Hz and the time is accurate to within ± 2%
 - the peak expiratory flow accuracy is ± 10% of the reading or 0.4 litres/sec, whichever is greater, at flow rates from 0-14 litres/sec
 - the FEF_{25-75%} range must be 7.0 litres/sec with an accuracy of ± 5% of the reading or 0.2 litres/sec, whichever is greater, over a minimum time of 15 seconds
 - the flow range must be 14 litres/sec with an accuracy of ± 5% of the reading or 0.2 litres/sec, whichever is greater at flow rates from 0 - 14 litres/sec
 - the MVV range must be 250 litres/min at a tidal volume of 2 litres with an accuracy of ± 10% of the reading or 15 litres/min whichever is greater at a flow range up to 14 litres/sec
 - the back pressure for MVV system must be less than ±10 cm H₂O at a 2 litre tidal volume at a frequency of 2 Hz. The resistance to airflow criteria for PEP, FEF_{25-75%}, and flow is the same as for FEV₁
 - flow type spirometers (such as capillary and screen pneumotachometers) where the flow signal is integrated to derive a volume may also be used. These instruments require different BTPS correction factors than volume spirometers as the assumption that no cooling of the air occurs as it passes through the flow sensor is usually made. This assumption can only be made if the flow sensor is heated to 37 degrees Celsius
 - manufacturers must be able to provide documentation that all spirometers meet the current recommendations (ATS/ERS Standardization of Spirometry, 2005)
- Illustrations of graphic record manoeuvres performed should adhere to ATS/ERS recommendations. The volume scale must be at least 10 mm/L (BTPS). The time scale must be at least 2 cm/sec. For flow volume curves, exhaled flow must be plotted upwards and exhaled volume to the right. A 2:1 ratio should be maintained for the volume and flow scales respectively
- A thermometer to measure ambient temperature, a barometer to measure atmospheric pressure and an hydrometer to measure humidity for the calculation of the BTPS factor.

The spirometer itself should also contain a thermometer for a more accurate calculation of the BTPS factor

Note: *Equipment recommendations referred to in this document are for diagnostic spirometers as opposed to those classified as monitoring devices.*

18.2.2 Technique

The technique for the forced expiratory spirogram and forced expired flow volume curve is the same. Using the closed-circuit technique, the patient is seated (preferably) in the upright position and is instructed to place the mouthpiece in the mouth so that no leaks are present. The patient's nose is then occluded with a nose clip. The patient is asked to breathe normally for 3 or 4 breaths to establish a constant end-tidal point. The patient is then instructed to inhale to total lung capacity and blow out to residual volume as forcefully as possible.

Using the open circuit technique, the patient inspires fully before inserting the mouthpiece and exhaling into the spirometer or pneumotachograph. A nose clip is not necessary when using the open circuit technique. Using this approach the patient does not inhale from the spirometer or flow sensor so no contamination of the inspired air can occur. The technologist must continually urge the patient to exhale until the "end of test" criteria are met. This occurs when there is:

- an obvious plateau in the spirometry tracing with no change in volume for at least 1 second after an exhalation time of at least 6 seconds for patient > 10 yrs of age, or an exhalation time of at least 3 seconds for patient < 10 yrs of age.

or

- the patient cannot continue.

The patient is then disconnected and allowed to rest. The spirometer is flushed between manoeuvres to prevent re-breathing of the carbon dioxide, which has accumulated during the manoeuvre.

Note: *If SVCs are performed they must be performed prior to the FVCs to avoid the possibility of premature bronchospasm.*

18.2.3 Measurements

The test is repeated until three acceptable SVC and three acceptable FVC tracings have been obtained. An acceptable tracing is one in which there is:

- maximal effort with no hesitation (extrapolated volume < 5% FVC or 0.15 L whichever is greater)
- no cough during the first second
- a smooth, continuous exhalation
- no glottis closure, obstruction of the mouthpiece or leaks
- end of test criteria is met

If the curve is deemed acceptable, the reproducibility criteria are then applied. The largest FVC or SVC and second largest FVC or SVC from acceptable manoeuvres must not vary by more than 0.15 L. For

forced exhalations, the largest FEV₁ and the second largest FEV₁ must not vary by more than 0.15 L. For patient with FVC or SVC \leq 1.0 L, a value of 0.10 L instead of 0.15 should be used.

The largest acceptable value is reported in litres at BTPS. FEF_{25-75%} is measured from the curve with the highest sum of FEV₁ + FVC using only the acceptable curves and is reported in litres/second at BTPS. FVL pictures, either printed or on screen must be available to the interpreting physician to review at the time of interpretation. These pictures must also be available either on screen or in printed format when un-interpreted results are sent to referring physicians as is often the case when patients have testing performed and see the physician on the same day, which means the referring physician is reviewing an un-interpreted copy of the test results. The final report should include the technologist's comments regarding unacceptable or non-reproducible data, including a description of the problem.

18.2.4 Calculations

Data calculation is automated in computerized pulmonary function systems, which includes all flow-type spirometers. Older volume-type-spirometer systems may require manually measuring and calculating the volumes and flows from a hard copy of the graphical recording.

For flow volume curves, measure the centimeter deflection on the **X** axis and convert to a volume (*on paper, usually 1 litre = 2 cm deflection*). Measure the centimeter deflection on the **Y** axis and convert to a flow (*on paper, usually 1 litre /sec = 1 cm deflection*).

For spirometry tracings, volume is represented on the **Y** axis and time is represented on the **X** axis (*for time 1 second is usually represented by 3 cm on paper*). Measure and record all acceptable values. Observed values are reported in BTPS and compared to predicted values from a healthy population of the same height, age and gender.

18.3 Quality Control

The spirometer volume is calibrated daily with a 3 L syringe. The measured volume should be within \pm 3.5% of the reading (*includes \pm 0.5% accuracy of the 3-L syringe*). Volume checks using at least 3 different flow rates from 0.5 -12 L/sec are necessary for flow-type spirometers. This requires 3 L injection times of approximately 0.5 - 6 seconds. The syringe must be accurate to within 15 ml for a 3 L syringe or at least 0.5% of the full scale deflection. The syringe must be re-calibrated as per manufacturer's specifications. The spirometer is checked for leaks daily by applying a pressure of 3 cm H₂O for 1 minute. A volume change greater than 30 ml after 1 minute indicates a leak. At least every 3 months volume spirometers are checked over the entire volume range in 1 L increments.

Flow spirometers must have their linearity checked at least weekly using different flow rates (low, mid, and high-range). Time is calibrated at least 4 times per year for non-computerized equipment. Laboratory testing with a healthy subject with known values is recommended. Laboratory testing of biologics should not exceed the established control mean \pm 2 SD. If computerized testing is done, (e.g., using a computerized FVC simulator), computer software adheres to ATS recommendations. Calibration procedures and results, calculations, reference values, preventive maintenance and corrective actions plus system hardware and software upgrades are maintained in a laboratory manual. The technical staff maintains records of continuing education, as well as feedback from the Quality Advisor regarding unacceptable test results and corrective action taken.

18.4 Infection Control

Nosocomial infections are a potential risk during pulmonary function testing. A clean mouthpiece and nose clip are used for each patient. Disposable filters are to be used unless the circuitry is changed after each patient or a non-rebreathing technique is used.

Note: *Please refer to the Provincial Infectious Diseases Advisory Committee of Public Health Ontario at <http://www.oahpp.ca/resources/pidac-knowledge>*

18.5 Sterilizing Equipment

There are many methods for sterilizing equipment. Manufacturer's recommendations should be followed. For mouthpieces, valves, tubing, etc., the most practical method is chemical sterilization in which equipment is completely immersed in a cold sterilizing solution for the recommended period of time depending on whether high-level disinfection or sterilization is required. The tubing and valves are processed at least daily. The mouthpieces and nose clips are processed after each use.

If equipment is contaminated with blood or sputum it must be sterilized immediately after it is used. Some chemicals will sterilize faster if they are heated. To eliminate toxic chemical residues, equipment is thoroughly rinsed and air dried before reusing.

Equipment that cannot be subjected to heat or chemicals must be sterilized using ethylene oxide (gas sterilization). The equipment must be thoroughly cleaned and packaged before it is sterilized.

Equipment sterilized by this method must be aerated for approximately 48 hours (or less if heat is applied) before use.

Note: *All equipment must be properly cleaned before undergoing disinfection and/or sterilization.*

18.6 Universal/Routine/Standard Precautions (URSP)

As many patients may have a potentially infectious disease, the facility must implement the nationally recognized program of Universal/Routine/Standard Precautions (URSP). Originating from the Center for Disease Control in Atlanta, Georgia, the principles of URSP apply to the management of patients and specimens.

URSP is a system which consistently interrupts the transmission of infections thus ensuring increased protection for both patients and health care providers. URSP are based on the premise that **ALL** patients are considered potentially infectious. Therefore, patients who are known to have infectious diseases are no longer singled out for special precautions. The exception to this is patients with known or suspected active tuberculosis.

Facility staff who are in contact with potentially infectious patients receive appropriate diagnostic follow-up.

These principles apply to both patients and patient specimens handled by clinical or diagnostic facilities, they include:

- effective handwashing before and after direct patient contact or contact with body substances
- wearing gloves for contact with blood, secretions, mucous membranes, non-intact skin, and moist body substances

- wearing additional barriers such as gowns, masks, protective eyewear, and plastic aprons when body substances are likely to soil clothing, skin, or mucous membranes
- containing soiled reusable articles, linen, and garbage securely enough to prevent leakage
- disposing of syringes and uncapped needles in a labeled puncture resistant container immediately after use

Chapter 19 Clinical Practice Parameters for Spirometry and Flow Volume Loop

19.1 Overview

Spirometry measures the volume of air an individual exhales as a function of time. Flow, or the rate at which the volume is changing as a function of time, may also be measured. Spirometry results correlate well with morbidity and life expectancy, but in certain situations, spirometry does not suffice and more extensive testing is warranted.

Any patient referred for assessment has flow rates measured, either by **spirometry** or a **flow volume loop**. In most instances, and assuming proper test performance and interpretation, spirometry will suffice. If properly performed, flow volume loops more readily detect inconsistent patient effort, and have the capacity to evaluate flow rates at lower lung volumes and during inspiration (to evaluate the extrathoracic upper airway).

Note: *Postbronchodilator studies (OHIP codes J324 & J327) should not be performed routinely; and neither should they be repeated routinely. (See bronchodilator section in this chapter)*
Postbronchodilator studies should not usually be performed if baseline spirometry is within normal limits.

19.2 Prerequisites

There are no prerequisites for this test.

19.3 Indications

Indications for spirometry pre or post bronchodilator include the need to:

- evaluate respiratory symptoms, especially dyspnea, wheeze, stridor and persistent cough
- evaluate abnormal laboratory tests, such as hypoxemia, hypercapnia, polycythemia, etc.
- diagnose an obstructive or restrictive ventilatory impairment, or an extrathoracic upper airway obstruction
- help assess peri-operative risk or exercise capacity
- determine baseline lung functions and monitor course of chronic obstructive lung diseases such as asthma and COPD
- monitor the course of chronic restrictive diseases, such as pulmonary fibrosis or a neuromuscular disorder
- evaluate the response to specific therapy for a respiratory condition
- help validate subjective complaints in occupational or environmental settings

- determine reversibility of airway obstruction as demonstrated by a reduced FEV₁/FVC ratio or other indicators of flow limitation
- evaluate alternative drug regimens in patients with known hyperreactive airways

19.4 Relative Contraindications

Forced expiratory manoeuvres should be performed with caution in the following circumstances:

- pneumothorax
- recent myocardial infarction or unstable cardiac status, ophthalmic surgery, abdominal surgery
- significant ongoing hemoptysis
- severe asthma
- presence or suspected presence of active tuberculosis or other communicable respiratory disease (febrile and severe respiratory illness)

19.4.1 Relative Contraindications for Bronchodilator Administration

- known or suspected adverse reactions to a specific bronchodilator
- unstable cardiovascular status (e.g., serious arrhythmias, significant tachycardia and elevated blood pressure) that might be aggravated by beta adrenergic stimulation

19.5 Reporting Guidelines

The largest vital capacity should be reported from all acceptable curves, including the forced manoeuvres (FVC). The largest FVC and the largest FEV₁ should be recorded after examining the data from all acceptable curves, even if they do not come from the same curve. Other measures, such as the FEF_{25-75%} and the instantaneous expiratory flows, should be obtained from the single curve that meets the acceptability criteria and gives the largest sum of FVC plus FEV₁ (i.e., best test).

The interpretation of spirometry involves two tasks:

- the classification of the derived values with respect to a reference population and assessment of the reliability of the data, and
- the integration of the spirometric values into the diagnosis, therapy, and prognosis for an individual patient.
- Comparison of patient measurement to predicted normal values, using 95% confidence limits to identify abnormal results.

The first task is the responsibility of the laboratory Quality Advisor or designate and serves not only to communicate information to the referring physician but also is an important aspect of laboratory quality control. The second task is ordinarily the responsibility of the physician requesting the studies and is performed within the context of patient care.

It is the responsibility of the Quality Advisor to develop explicit procedures for interpretation of spirometry and to select appropriate reference values.

The spirometry report includes a description of the type of ventilatory abnormality seen, with a comparison of the patient's results to the predicted values. If a suboptimal performance is suspected or evident, this should be noted. Any current medications, dosage, and time taken should also be noted.

Note: *Abnormalities of flow at lower lung volumes (FEF25-75% and instantaneous expiratory flows) are more variable than a FEV1 and must be interpreted with caution. Small airways dysfunction may be an early indicator of disease, but such abnormalities are not always predictive of future impairment.*

19.5.1 Bronchodilator Administration

A standardized assessment of bronchodilator response is necessary as many factors affect the bronchodilator response including type and amount of medication and method of delivery used.

Beta-adrenergic aerosols are the most commonly used form of bronchodilator for pre- and post-testing. The evaluation of other drugs can be conducted if requested by referring physicians. In order to effectively evaluate a response to beta-adrenergic drugs the medications below should be withheld for these recommended times:

MEDICATION		LENGTH OF ABSTENTION
Inhaled bronchodilators	Short-acting	4 to 8 hours
	Long-acting	24 hours
Anticholinergics		6hours
Oral short-acting bronchodilators		8hours
Sustained release beta-agonists		24 hours
Theophyllines	Twice-daily preparation	24 hours
	Once-daily preparations	48 hours

If the aim of the test is to determine whether further improvements in lung function are possible with a specific therapy, the above medications may not need to be withheld. The time between pre and post testing depends on the time to peak effect for the drug used. This is approximately 15 minutes for short-acting beta-agonists. Other drugs, such as anticholinergics may require a longer interval before retesting.

The recommended method for drug administration is 4 separate doses at approximately 30 seconds intervals of 100 µg of a β-agonist, inhaled in one breath to total lung capacity via a metered-dose inhaler (MDI). The breath is then held for 5-10 seconds. This will maximize deposition of the drug in the lungs. A lower dose may be used if side effects of the β-agonists are of concern for the patient. If anticholinergics are used, the method is the same, but the dose is 8 puffs of 20 µg of medication. The post bronchodilator testing is performed 10-15 minutes after administration of short-acting β2-agonists and 30 minutes after administration of short-acting anticholinergic medications. If less than the recommended dosage is used the clinical reasons should be reported.

Interpretation of the response to inhaled bronchodilators is based on both absolute and percent change in function. Evaluating the response to bronchodilators is most commonly done by measuring and comparing forced expiratory volume in one second (FEV₁), forced vital capacity (FVC) and peak expiratory flow (PEF) before and after bronchodilator administration.

If postbronchodilator studies are performed, only significant responses are reported as positive. An increase in either FEV₁ or FVC of 12% or more over baseline represents a definite response (provided

there is an absolute increase of at least 200 mL). The clinical relevance of 10-12% increases in flow rates is controversial. On the other hand, negative studies also need to be interpreted with caution. In addition, an increase in SGaw of 35% or more over baseline represents a significant bronchodilator response in adult patients.

Note: Failure of flow rates to increase by 10-12% at one sitting does not rule out reversibility of airflow obstruction under other circumstances (e.g., time of day, choice of bronchodilator, dose of bronchodilator, ancillary therapy, duration of therapy, etc.)

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Independent Health Facilities: Clinical Practice Parameters and Facility Standards

Pulmonary Function Studies

Volume 4 Oximetry

Chapter 20 Facility Standards for Oximetry

20.1 Staffing

An IHF performing oximetry only should employ at a minimum the following for patient care and consultation:

- Quality Advisor
- Physician
- Technologist (optional)

Please see Volume 1 Chapter 2 for qualifications, roles and responsibilities.

20.2 Equipment

Equipment accuracy is determined by regular calibration checks. The results obtained must conform to recognized standards. The frequency of calibration is mandated by documents of the ATS (American Thoracic Society) and ERS (European Respiratory Society) standards for spirometry, lung diffusion and lung volumes. Physicians and staff must be fully familiar with the most current recommendations of the ATS/ERS regarding pulmonary function standards.

Each facility must establish a Quality Control Program to monitor that the equipment used produces measurements within acceptable limits of accuracy and precision of a test procedure.

20.3 Quality Control

The equipment calibration and quality control must include the following:

- Records of acceptable operation of new equipment or equipment after repairs or other alterations
- Records of calibration and quality control logs
- Records of updates or changes in computer software, hardware and pulmonary function equipment operating system

Part of the quality control activities is data collection and analysis. All calibration and quality control data should be properly analyzed and plotted. The technologist must be familiar with the terms and definitions used in the quality control program. The following “Terms and Definitions” are obtained from Chapter 5 (pg. 1-2), “Quality Control of the Pulmonary Function Laboratory Management Manual, 2nd Edition by ATS, 2005.

20.3.1 Terms and Definitions

- Accuracy: How well the measurement reflects the true or correct value.

- Precision: Measurement variability (repeatability); it is completely independent of accuracy or truth.
- Random errors: Errors that occur without prediction or regularity, tend to decrease precision and often result from inherent variation in the instrumentation.
- Systemic error: Errors within the test system or methodology (e.g., instrument calibration or malfunction) that tend to produce bias.
- Biologic Standard: Healthy non-smoking individual used in quality control
- Standard deviation (SD): A measurement of variability or tendency of values to vary from the arithmetic mean. It is the square root of the variance.
- Coefficient of variation: A mathematical expression of variability calculated by dividing the SD by the mean.

20.4 Electrical Safety

All equipment used at the facility must be CSA approved.

Staff should learn how to correctly operate and care for the electrical equipment used in the facility. Cords, plugs, and outlets are routinely checked for damage. All receptacles are of the three-prong type. If any piece of electrical equipment appears to operate in an abnormal manner (strange noises or hums, sparks, fuzzy tracings, etc.) it must be removed and repaired by a qualified person. If possible, do not touch an electrical device with one hand and a patient with the other hand.

20.5 Infection Control

Resources are available through the **Provincial Infectious Diseases Advisory Committee** of Public Health Ontario, *Infection Prevention and Control for Clinical Office Practice June 2013*
http://www.publichealthontario.ca/en/eRepository/PIDAC_Cleaning_Disinfection_and_Sterilization_2013.pdf

Note: Facilities should visit the website at least annually, during the review of their policies and procedures manual, to obtain the most recent updates.

Nosocomial infections are a potential risk during pulmonary function testing. A clean mouthpiece and nose clip is used for each patient. Disposable bacterial filters are to be used unless the circuitry is changed after each patient.

Most infectious diseases are transmitted by direct contact with contaminated equipment or an airborne route. An infection control program to reduce the risk of transmission to an acceptable level – realizing that zero risk is not attainable – includes:

- reprocessing used equipment
- routine practices

- droplet precautions (for febrile and severe respiratory illness)
- airborne transmission precautions (for tuberculosis)

20.6 Cleaning, Disinfection and Sterilization of Equipment

20.6.1 Cleaning

Cleaning is the first important step in reprocessing equipment. Effective cleaning will maximize the efficacy of any subsequent disinfection or sterilization process. An item that is not properly cleaned cannot be disinfected or sterilized with assurance.

Effective cleaning can physically remove a large number of microorganisms. Soil or other foreign material can shield and protect microorganisms or even interact to neutralize the action of the disinfectant or sterilant. Furthermore, after glutaraldehyde treatment, which acts as a fixative, any organic material left on the item is extremely difficult to remove.

The cleaning of used and contaminated equipment consists of the following:

- Sorting and soaking
- Removal of organic material
- Rinsing
- Drying

20.6.2 Disinfection and Sterilization

There are many materials and methods for disinfecting and sterilizing equipment. Manufacturers' recommendations should always be followed. Pulmonary function equipment is classified as semi-critical items and requires high-level disinfection. For detailed information regarding cleaning, disinfection and sterilization of medical instruments please refer to the **Provincial Infectious Diseases Advisory Committee** of Public Health Ontario at <http://www.oahpp.ca/resources/pidac-knowledge>

If equipment is contaminated with blood or sputum it must be sterilized immediately after it is used. Some chemicals will sterilize faster if they are heated. To eliminate toxic chemical residues, equipment is thoroughly rinsed and air dried before reusing.

Equipment that cannot be subjected to heat or chemicals must be sterilized using ethylene oxide (gas sterilization). The equipment must be thoroughly cleaned and packaged before it is sterilized. Equipment sterilized by this method must be aerated for approximately 48 hours (or less if heat is applied) before use.

20.7 Infection Control Program

Infection control consists of evidence-based practices and precautions used to prevent the transmission of pathogens causing infection, and includes the knowledge and skills required to implement appropriate interventions. Infection control practices are intended to protect patients, health care workers, and the public from exposure to infectious diseases. The infection control program is designed to reduce the risk of transmission to an acceptable level – realizing that zero risk is not attainable – by taking the appropriate isolation precautions.

20.7.1 Routine Practices

Routine practices describe the system of practices recommended by Health Canada (Standard Precautions is the counterpart term used by the US Centers for Disease Control and Prevention) which incorporates the blood borne pathogen precautions or Universal Precautions (UP) and non-blood borne pathogen precautions or Body Substance Precautions (BSP). Routine practices are designed to reduce the risk of transmission of pathogens from blood, all body fluids, secretions, excretions, and drainage of wounds from all patients (are considered potentially infectious) regardless of infection status.

Routine practices, or its equivalent, should be used during all patient care, and includes:

- Hand washing or cleansing with an alcohol based sanitizer before and after any direct contact with a patient.
- The use of additional barrier precautions to prevent health care worker contact with a patient's blood, body fluids, non-intact skin or mucous membranes.
- The wearing of surgical masks and eye protection or face shields where appropriate to protect the mucous membranes of the eyes, nose and mouth during procedures and patient care activities likely to generate splashes or sprays of blood, body fluids, secretions, and excretions.
- Gloves are to be worn when there is a risk of body fluid contact with hands; gloves should be used as an additional measure, not as a substitute for hand washing.
- Gowns are to be worn during procedures and patient care activities likely to generate splashes or sprays of blood, body fluids, secretions, and excretions that could contaminate uniform or clothing.

20.7.2 Droplet Precautions

Droplet precautions describe the type of precaution designed to reduce the risk of droplet transmission of infectious diseases. Droplet transmission involves contact of the mucous membrane of the eyes, nose, and mouth of a susceptible person (host) with large particle droplets containing pathogenic microorganisms generated from a person who exhibits a clinical disease or who is a known or suspected carrier of the pathogenic microorganism (source). The source person generates these droplets from coughing, sneezing, talking, or performing pulmonary function tests. Transmission via large particle droplets requires close contact between the source person and susceptible host because these droplets (larger than 5 µm in size) do not remain suspended in the air and generally travel through the air short distances of 1 meter (3 feet) or less. In addition to routine precautions, droplet precautions should be used for a patient with known or suspected to have a droplet transmitted infection.

Droplet precautions consists of:

- Placing the source person in a single room if possible, or separated from other people by at least 1 meter and minimizing the time spent in the waiting room.
- Wearing a water resistant surgical or procedural mask and eye protection or face shield.

20.7.3 Airborne Precautions

Airborne precautions describe the type of precaution designed to reduce the risk of airborne transmission of infectious diseases. Airborne transmission occurs by dissemination of airborne droplet nuclei (smaller than $\mu 5$ m in size) evaporated from larger droplets or dust particles containing microorganisms that remain suspended in the air for long periods of time. Microorganisms carried in this manner can be widely dispersed by air currents and inhaled by susceptible hosts over a longer distance (in the same room or different rooms) from the source person. There is evidence of airborne transmission of source patients with tuberculosis.

Airborne precautions consist of:

- Patients suspected of having active pulmonary TB should not have pulmonary function tests until this diagnosis is excluded.
- Placing and confining the patient with known or suspected infectious tuberculosis in an examining room keeping the door closed at all times. This room should have negative pressure relative to the surrounding areas with exhaust vented outside or filtered through high-efficiency filters if recirculated to other areas in the facility.
- Wearing special high-efficiency masks with adequate facial seal (N95 respirator) when entering room of patient with known or suspected infectious pulmonary tuberculosis.

Because pulmonary function laboratories may be asked to evaluate individuals with symptoms consistent with active pulmonary tuberculosis (TB), transmission to other patients and health care workers remains a potential risk. TB remains an important potential occupational hazard in health care facilities that serve populations at high risk (including Aboriginal Canadians, the inner city poor, or emigrants from countries in Asia, Eastern Europe, Africa and Latin America where TB is still common).

Recent U.S. reports have documented outbreaks of multi-drug resistant TB in health care facilities, and also the failure of these facilities to implement appropriate TB control measures. In these outbreaks, 18 to 35 percent of exposed workers had documented conversions on tuberculin testing; health care workers infected with HIV are particularly susceptible. A consistent contributing factor to nosocomial outbreaks is a delay in diagnosis, due to lack of physician awareness, atypical clinical presentations or inadequate diagnostic facilities. BCG does not confer complete protection; TB can still occur in vaccinated health care workers.

It is very difficult to estimate precisely the infectiousness of an index case, but infectiousness is higher if the patient has extensive disease on chest radiographs, positive sputum smears for acid-fast bacilli, or is not receiving effective therapy. A patient with frequent cough or who undergoes cough-inducing procedures is also thought to be more infectious.

All health care workers are under an ethical and legal duty to both protect the health of their patients and to maintain confidentiality. Staff with symptoms compatible with tuberculosis should seek advice from Occupational Health or from their own doctor so that they do not expose patients to infection.

Recent Canadian guidelines do not specifically address TB precautions in pulmonary function laboratories. By inference, however, recommendations might include:

- All staff should be aware of the infection control guidelines for patients with known or suspected tuberculosis.

- Patients suspected of having active pulmonary TB should not have pulmonary function tests until this diagnosis is excluded.
- When a patient with active tuberculosis is tested before the diagnosis is known, identification of the contacts in the Lab at the time of testing, and immediate notification of the Public Health Department are required.
- Lab personnel should undergo two-step tuberculin testing before employment and have regular tuberculin skin tests thereafter.

In pulmonary function labs that serve populations at high risk, appropriate ventilation strategies should be employed. The relative cost-effectiveness of adequate ventilation, ultraviolet light and personal masks/ respirators remain controversial. Front-line personnel should consider the use of high-efficiency particulate air filter (HEPA) masks.

20.8 Latex Anaphylaxis

Natural rubber latex is a common component of many medical supplies. Although most often associated with disposable gloves, other items which contain latex include airways, intravenous tubing, syringes and stethoscopes. The reporting of allergic reactions to latex has dramatically increased in the past 10 years. Frequent users of latex products may develop allergies to latex proteins, with resulting allergic reactions varying from mild to life-threatening.

20.8.1 Providing a Latex-Safe Environment

A latex-safe environment should be the goal of every health care facility. Latex has been used in the manufacture of pulmonary function circuits, and especially in disposable mouthpieces, nose clips and tubing. While reported reactions in exposed patients are rare, it would appear prudent to use latex-free products wherever possible. Emergency carts with latex-free medical products should be available.

20.9 Emergency Procedures

Emergency policies and procedures are documented in the facility manual and must include medical emergencies and fire safety.

20.9.1 Fire Safety

It is each staff person's responsibility to be aware of the facility's policies and procedures with respect to fire safety and fire prevention. Common sense is stressed so that emergency exits are not blocked and fire barrier doors are not propped open. A fire manual is available and reviewed twice a year. It includes the responsibilities for fire prevention, the classes of fires and extinguishers, steps on discovery of a fire, plans for reporting fires, fire evacuation plans, and maps. Fire numbers are posted on all telephones. Appropriate fire extinguishers are easily accessible and are checked each month and replaced if outdated or used.

When a fire is discovered:

- remove patients from immediate danger
- enclose area, close doors and windows upon leaving
- turn lights on
- turn off gas cylinders
- activate alarm
- call fire department, give location, your name, and type of fire
- try to extinguish the fire only if it is feasible

An evacuation plan is prepared and is practised periodically

For specific fire safety prevention and evacuation procedures, contact your local fire department.

20.10 Policies and Procedures Manual

Written policies and procedures are available for but not limited to the following:

- Overview of the lab
- Scope and Limitation of services
- General office policies and procedures
- Emergencies – Fire, Police, Hospitals
- Policies and procedure for record structure, maintenance and storage & destruction
- Confidentiality policies
- Consent and Privacy Policies and Procedures
- Reporting Policies and Procedures
- Equipment list including routine maintenance, validation and calibration of equipment (logs to be maintained separately for these procedures)
- Infection Control
- General policies on dealing with and documenting incidents and complaints including follow-up.

20.11 Quality Management

The facility must institute a Quality Management Program. It is recognized that quality management programs will vary depending on the facility size, scope of practice, and geographical considerations. Please refer to Chapter 5 Volume 1

20.12 Requesting and Reporting

20.12.1 Pulmonary Function Requisition

Basic demographic information is included on the Pulmonary Function Studies Requisition. Reserve an area at the upper right hand corner of the form for the Health Number imprint. The form is dated appropriately; the format is day, month, and year.

The information collected includes the patient's family name, first name and initial, address, postal code, and any cultural or religious beliefs which may affect medical care (e.g., Jehovah's Witness). Unless a latex-safe environment has been provided, questions regarding latex allergy should be asked of all patients. Clinical information such as the presence of dyspnea, cough, or wheeze, is included in the requisition, as well as a list of the relevant medications that the patient is taking. Details of the patient's smoking history are also useful.

A working diagnosis and area for further comments is also present. The reason for testing is outlined on the requisition.

20.12.2 Test Results

The facility retains the original results of all measurements made for each test for a period of time as specified by the IHFA Regulations. See Appendix I Independent Health Facilities Act - Ontario Regulation 57/92.

20.12.3 Test Report

A report is provided to the referring physician for each test performed in the facility. Copies of all reports are retained with the requisition and original data for a period of time as specified by the IHFA Regulations.

The report includes the following information:

- personal data (height in centimetres, weight in kilograms) sufficient to identify the patient, the patient's age, height, and weight; the referring and reporting physicians, the name of facility performing the test, and the test date.
- the technologist's comments as to the reliability of the patient's performance during the test, where necessary.
- a summary of the original data obtained and calculations made during the test and, of the graphical records.
- Comments concerning changes or an absence of change
- the reporting physician's interpretation of the original data as well as, where appropriate, comments as to the relevance of the results to the patient's presenting problem or suggestions as to patient management arising from the results.

20.12.4 Report Form

The report form contains the same demographic information as the requisition and is dated appropriately. Where applicable, the lower limit of normal and percent predicted should be included in the report. The results can be expressed in a variety of ways (e.g., numerically or graphically), but should express readily the results of the test. Normal ranges for the results, appropriate to the tested individual, are included. The interpreter's signature completes the report.

Requisitions and report forms (preferably the originals) should be kept at the facility and should be available for inspection. Following a telephone requisition, the requisition must be signed by the requisitioning physician.

A written requisition from the referring physician is required by all facilities as stipulated in the Regulations under the Independent Health Facilities Act.

Chapter 21 Clinical Practice Parameters for Oximetry

List of main abbreviations

COHb= carboxyhemoglobin	MetHb= methemoglobin
F _I O ₂ = inspired O ₂ fraction	P _a O ₂ = arterial partial pressure for O ₂
Hb= deoxyhemoglobin	P _A O ₂ = alveolar partial pressure for O ₂
HbO ₂ = oxyhemoglobin	SaO ₂ = arterial O ₂ saturation
HR= heart rate	SpO ₂ = O ₂ saturation by pulse oximetry

21.1 Overview

Oxygen saturation by pulse oximetry (SpO₂) is a non-invasive estimate of hemoglobin O₂ saturation using the absorption of different wave lengths of light from oxygenated (HbO₂) and deoxygenated (Hb) hemoglobin. Pulse oximeters have 2 LEDs (light emitting diodes) one in the red region (660nm) and one in the infrared region (940nm). Oxygenated hemoglobin absorbs more infrared light and allows more red light to pass through. Deoxygenated hemoglobin allows more infrared light to pass through and absorbs more red light. HbO₂ absorbs less light in the red region of the optical spectrum (660nm) than does Hb therefore reflecting it as red and oxygenated blood is distinctively red, whereas deoxygenated blood has a characteristic dark blue colour. The difference in transmission of 660nm vs 940nm wavelength can then be used to calculate the amount of oxygenated hemoglobin.

Determining SpO₂ allows for the non-invasive estimation and monitoring of blood oxygenation. Decreases in SpO₂ indicate the presence of hypoxemia, i.e. reduction in O₂ concentration within the arterial blood. Hypoxemia is a major cause of impaired tissue O₂ delivery and hypoxia (low tissue PO₂) as most of the O₂ available in arterial blood is bound to Hb. The SpO₂ is usually obtained from the fingertip, forehead, or earlobe at rest, exercise, or different levels of supplemental O₂. Many of the studies on pulse oximetry employed healthy volunteers (for derivation of calibration curves) and relatively few investigations were done in ambulatory patients with cardiopulmonary disease. Measurements obtained from a pulse oximeter are typically SpO₂ and pulse rate, which is equivalent to heart rate. Common clinical applications of determining SpO₂ are at rest, sleep and exercise.

21.2 Prerequisites

There are no prerequisites for this test.

21.3 Indications

Indications for this test include the need to:

- estimate SpO₂ if there is a clinical suspicion of desaturation, in association with exertional dyspnea, lung disease or a reduced diffusing capacity
- document changes in SpO₂ with exercise, (usually in patient with SpO₂ >90% at rest)

- monitor changes in SpO₂ during sleep
- document improvement in oxygen desaturation following change in therapy or in level of O₂ supplementation with or without exercise

Note: Routine use of oximetry to determine oxygen saturation at rest without any clinical indication is not an appropriate standard of care.

21.4 Contraindications

Exercise oximetry should not be performed in patients with uncontrolled systemic hypertension, unstable angina pectoris, or those who have had a systemic or pulmonary embolism, or a myocardial infarction within the last four weeks.

21.5 Instrumentation

Pulse oximeter with a probe for attachment to a peripheral site (e.g., finger, ear, forehead). A probe for more than one site must be available.

21.6 Techniques

The patient should have refrained from smoking or from inhaling second hand smoke for one hour. Ask the patient if he/she has symptoms compatible with Raynaud's phenomenon. If that is the case, an ear or forehead transreflectance probe may be used. Apply the probe to a clean site. Consider heating the extremity where the probe will be applied as SpO₂ is dependent upon adequate arterial blood flow. Nail polish and/or artificial acrylic nails must be removed prior to testing. Do not use an inflated blood pressure cuff on the same limb as the oximeter probe. If oxygen saturation was measured also during exercise, observe the patient for 3 to 5 minutes post exercise for cardiac or neurological signs or symptoms.

21.7 Measurements

SpO₂ and heart rate (HR) can be obtained from the digital display and printout. A hardcopy of measurements (print out or manual documentation) must be available. The plethysmographic waveform and signal strength indicator must be used to assess validity of the data. A comparison of pulse oximeter heart rate reading to one from palpation and an ECG, if available, can be used to check adequate perfusion at the probe site.

21.8 Reporting Guidelines

Resting oximetry is performed in the sitting position, if different, it must be documented

The inspired oxygen used by the patient (room air or supplemental oxygen) should be documented.

If SpO₂ is measured at a different levels of inspired O₂, then up to 20 minutes equilibration time may be required between determinations.

If saturation is continually monitored, a change in value of 4% between different levels of inspired O₂ or during exercise means that there has been a real change in saturation, but the significance requires clinical interpretation.

Report hypoxemia at rest and/or exercise if SpO₂ ≤ 88%.

Table 1: Key variables to be reported

Variable	Symbol	Unit	Comment
Oxygen saturation by pulse oximeter	SpO ₂	%	
Heart rate	HR	bpm	
Supplemental O ₂		%	for Venti-mask
		L/min	for nasal cannula

Limitations of Procedure

Substantial reductions in arterial partial pressure for O₂ (P_aO₂) can be missed by the isolated analysis of SpO₂ due to the sigmoid shape of the HbO₂ dissociation curve. P_aO₂ rather than SaO₂ is the main drive for ventilatory stimulation through the carotid bodies. A normal SpO₂ in the presence of an elevated inspired O₂ concentration provides little or no information on the adequacy of patient ventilation. In fact, owing to the curvilinear relationship between alveolar (A) ventilation and “mean” P_AO₂ plus the presence of substantial (A-a) O₂ gradient there is an inherent delay for P_aO₂ to reflect acute decreases in P_AO₂ induced by hypoventilation. For these reasons, oxygen saturation cannot be used to determine the adequacy of patient ventilation.

Situations or outside interference may affect pulse oximeter readings, limit precision or limit the performance of a pulse-oximeter instrument (**Table 2**).

- Motion artifact can interfere with pulse oximeter measurements. Some pulse oximeters are better than others at rejecting motion artifact.
- COHb falsely elevates SpO₂ values; high MetHb values cause falsely low values on pulse oximeters when the O₂ saturation is >85%, and falsely high values when O₂ saturation is <85%.
- Low perfusion states from vasoconstriction.
- Nail polish or acrylic nail coverings can alter oximetry readings when a finger probe is used; black, blue, and green nail polish significantly lower readings. It is recommended that any nail polish be routinely removed before finger probes are used for pulse oximetry measurement.

- Inability to detect saturations below 83% with the same degree of accuracy and precision as at higher saturations.
- Inability to quantify the degree of hyperoxemia present.
- Hyper-bilirubinemia has been shown NOT to affect the accuracy of SpO₂ readings.
- Skin pigmentation may be associated with slightly elevated saturation values.

Table 2: Factors known to interfere with pulse oximetry at the point-of-care

• Inadequate peripheral perfusion
• Incorrect probe position
• Nail varnish (specially acrylic)
• Atrial fibrillation and other possible arrhythmias
• Insufficient warming
• Motion-related artefacts
• Carboxyhaemoglobin
• Methaemoglobin-induced bias towards 85%
• Overestimation in some patients with sickle cell disease
• Intravenous dyes
• Increased venous pulsation (tricuspid incompetence)
• External electrical and optical interference

22.8.3 Validation of the Oximeter

Oximeter validation annually by a Biomedical Facility equipped with an oximeter simulator is strongly recommended.

22.8.4 Normal values for Oximetry(2)

Resting SpO₂ on room air for:

Age (18-44)	≥ 96%
Age (45-64)	≥ 94%
Age (>64)	≥ 93%

21.9 Quality Control

A self-check routine for the functionality of the oximeter is initiated when the unit is switched on. The operator should not use the oximeter if the self-check routine has failed.

With conventional pulse oximetry, the instruments are generally accurate to as low as 83% saturation when patients are being tested under steady state conditions. When using the older standard oximeters, check the manufacturers' recommendations for accuracy ranges. Skin thickness and skin pigmentation can affect the results obtained from oximetry.

For the saturation to accurately reflect steady state conditions, the patient must be continuously breathing a given F_iO_2 for a minimum of 5 minutes and possibly as long as 20 minutes, depending on the degree of airflow limitation, prior to the measurement being recorded.

Biologic controls should be monitored and documented monthly.

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Chapter 22 6-Minute Walk Test (6MWT)

List of main abbreviations

6MWT: 6- minute walk test	MCID: minimal clinically-important difference
6MWD: 6- minute walk distance	SpO ₂ : O ₂ saturation by pulse oximetry
HR: heart rate	

22.1 Overview

The 6- minute walk test (6MWT) is commonly used to assess response to a medical or surgical intervention in subjects with moderate to severe heart or lung disease and to evaluate functional capacity. It is a simple test that assesses patients' ability to walk without sophisticated equipment (1). The test is reproducible (8%) and simple to perform. The 6MWT might provide a good index of the ability to carry out daily activities. The information from the 6MWT is complimentary to **Cardiopulmonary Exercise Testing**, the test of choice to determine maximal exercise capacity and the mechanisms of exercise limitation (**See Chapter 15, Cardiopulmonary Exercise Test**).

22.2 Pre-requisites

Facility Requirements

- A 30 m-long, unobstructed (clear of obstacles and traffic) and straight-line walking course must be available
- The walking course should be marked at 3-meter intervals
- Orange traffic cones should be placed at the starting (0-meter) and 30-meter turnaround points
- Testing should be performed in a location where a rapid, appropriate response to an emergency is possible.
- The appropriate location of a crash cart should be determined by the physician supervising the facility.
- Supplies that must be available include oxygen, sublingual nitroglycerine, aspirin, and salbutamol (metered dose inhaler or nebulizer). A telephone or other means should be in place to enable a call for help.

22.3 Indications

Exercise-related O₂ desaturation

- Interstitial lung disease
- COPD

Functional Status

- COPD

- Interstitial lung disease
- Heart failure
- Peripheral vascular disease

Predictor of morbidity and mortality

- COPD
- Heart failure
- Pulmonary hypertension

Pre-treatment and post-treatment comparisons

- Lung surgery
- Pulmonary rehabilitation
- Pulmonary hypertension
- COPD
- Heart failure

22.4 Contra-Indications

Absolute:

- unstable angina during the previous month
- myocardial infarction during the previous month

Relative:

- resting heart rate of more than 120,
- systolic blood pressure of more than 180 mm Hg,
- diastolic blood pressure of more than 100 mm Hg.

Patients with any of these findings should be referred to the physician ordering or supervising the test for individual clinical assessment and a decision about the conduct of the test. The results from a resting electrocardiogram done during the previous 6 months should also be reviewed before testing. Stable exertional angina is not an absolute contraindication for a 6MWT, but patients with these symptoms should perform the test after using their antiangina medication, and rescue nitrate medication should be readily available.

22.5 Indications for test termination

- chest pain
- intolerable dyspnea
- leg cramps
- staggering
- diaphoresis (sweating)
- pale or ashen appearance

22.6 Instrumentation and Supplies

- Pulse Oximeter
- Countdown timer (or stopwatch)
- Lap counter (mechanical or counter on worksheet)
- Two small orange cones to mark the turnaround points
- A chair or wheelchair for patient to sit in an emergency
- Worksheets on a clipboard
- A source of oxygen with nasal cannula
- Sphygmomanometer and stethoscope

22.7 Technique

22.7.1 Pre-Test Procedures

- Physicians are not required to be present during all tests. However, the supervising laboratory physician may decide whether physician attendance at a specific test is required.
- Check physician's order for 6 MWT with or without supplemental oxygen.
- When switching from room air to supplemental oxygen or vice and versa, a minimum of 10 minutes should be elapsed before starting the walk test.
- Comfortable clothing with walking shoes (sneakers)
- Patients should use their usual walking aids during the test (cane, walker, rollator etc.)
- Patients should take their medications as usual
- No meals and no vigorous exercise within 2 hours before test
- Patients should not wear nail polish or artificial acrylic nails
- Height and weight must be accurately measured
- Patient should rest for at least 10 minutes in a chair near the starting point. During the 10 minutes rest, attach the oximeter probe to ensure that the SpO₂ and heart rate (HR) signals are acceptable and optimal. Using Exercise Oximetry Worksheet (*see pg 165*), record at least the last 5 minutes of SpO₂ and heart rate readings.
- Before walking start, rate and record patient's dyspnea (shortness of breath) level using the Borg Scale (*see pg 164, Borg Scale*) while patient is standing at the starting point.
- A “warm-up” period before the test should not be performed.
- Carefully explain to the patient the objective of the test and state clearly that ***“The object of this test is to walk as far as possible for 6 minutes. You will walk back and forth in this hallway. You are permitted to slow down, to stop, and to rest as necessary. You may lean against the wall while resting, but resume walking as soon as you are able.”***

22.7.2 Test Procedure

- Do **not** walk with the patient unless patient is a fall risk even with the walking aids.
- Do **not** talk to anyone other than the patient during the walk.
- Watch the patient and do not get distracted and lose count of the laps.

- Keep conversation to the minimum. **Use an even tone of voice to communicate with the patient for concerns or words of encouragement.**
- Record the SpO₂ and heart rate at a periodic time interval (e.g.: 30 seconds interval) and when every lap is completed (*see Exercise Oximetry Worksheet pg 165*).
- Patient is allowed to rest if needed to and resume walking as soon as patient is able to continue (number of rests are recorded).
- At the end of 6 minute mark, stop the patient and note the distance of the partial lap walked in meters. Rate and record patient's dyspnea level using the Borg Scale immediately.
- If O₂ supplementation is needed during the walks and serial tests are planned, then during all walks by that patient O₂ should be delivered in the same way with the same flow. If the flow must be increased during subsequent visits due to worsening gas exchange, this should be noted on the worksheet and considered during interpretation of the change noted in 6MWD.
- The type of O₂ delivery device should also be noted on the report: for instance, the patient carried liquid O₂ or pushed or pulled an oxygen tank, the delivery was pulsed or continuous, or a technician walked behind the patient with the oxygen source (not recommended).
- Measurements of pulse and SpO₂ should be made after waiting at least 10 minutes after any change in oxygen delivery.

22.7.3 Post-procedure

- Ask the patient to sit and rest in a chair for recovery; continue to monitor the SpO₂ and HR for 2 minutes. Remove oximeter probe if the 2-minute post walk SpO₂ and heart rate are returning close to the pre walk values.
- Calculate the 6-min walk distance (6MWD) from adding the total laps walked multiply the distance per lap (e.g. 30 m) and the partial distance walked in meters at the end of 6 min mark.

22.8 Reporting Guidelines

- See Sample of Exercise Oximetry Report pg 166.
- Report HR from low to high values for the duration of the walk
- Report the SpO₂ from high to low for the duration of the walk
- Calculate the 6MWD and compare it against the lower limit of normal and percent predicted.

22.9 Interpretation

A sample of reference values is provided below: note that the lower limit (LLN) of is at least 100 m below the predicted value (6). Absolute values are also valuable to predict mortality and severe dysfunction: a value <350 m has been widely used in this context in patients with COPD (7).
6MWD Reference Value for aged 40 – 80 (Enright PL, 1998)

Male:

$$\text{Predicted} = (7.57 \cdot \text{Ht}) - (5.02 \cdot \text{A}) - (1.76 \cdot \text{Wt}) - 309$$

$$\text{LLN: (Predicted -153)}$$

Female:

$$\text{Predicted} = (2.11 \cdot \text{Ht}) - (2.29 \cdot \text{Wt}) - (5.78 \cdot \text{A}) + 667$$

$$\text{LLN: (Predicted -139)}$$

6MWD Reference Value for age 68 years and older (Enright PL, 2003)

Male:

$$\text{Predicted} = 493 + (2.2 \cdot \text{Ht}) - (0.93 \cdot \text{Wt}) - (5.3 \cdot \text{A}) + 17$$

$$\text{LLN: (Predicted - 100)}$$

Female:

$$\text{Predicted} = 493 + (2.2 \cdot \text{Ht}) - (0.93 \cdot \text{Wt}) - (5.3 \cdot \text{A})$$

$$\text{LLN} = (\text{Predicted} \cdot 0.75)$$

Where:

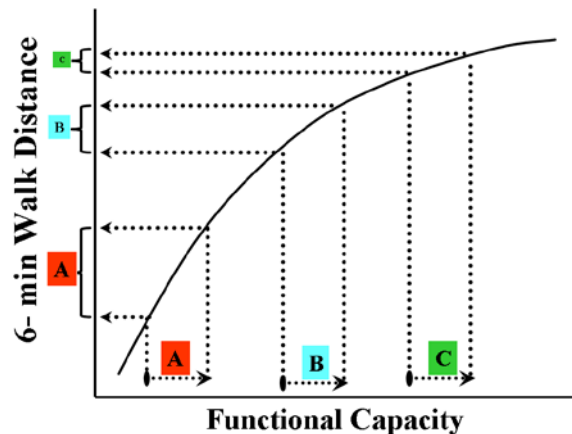
Ht = Height in centimeter (cm)

Wt = Weight in kilogram (kg)

A = Age in years

Although an influential firstly study suggested that the minimal clinically-important difference (MCID) for the 6-MWD was in the range of 50-80 m in patients with COPD (8), more recent data indicate that it might be as low as 25-30 m in more severe patients (6,7,9). In fact, a reduction in the 6MWD of 30 m or more has been associated with increased risk of death in these patients (7). Similar MCID values have been reported in interstitial lung disease and heart failure (10,11). It should be noted, however, that the test becomes less sensitive to unravel the effects of interventions as the patients walks longer at baseline (or improve over time)(Figure 1).

Figure 1: Impact of similar changes in functional capacity (FC) (arrows) according to patient's baseline 6-min walk distance (6-MWD). Due to the curvilinear relationship between FC and 6-MWD, the 6-MWD tends to become less sensitive the greater the baseline value.



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Chapter 23 Exercise Oximetry for Home Oxygen Assessment

List of main abbreviations

6MWT: 6-minute walk test	HR: heart rate
6MWD: 6- minute walk distance	SpO ₂ : O ₂ saturation by pulse oximetry

23.1 Overview

Home Oxygen Program (HOP) is administered through the Assistive Devices Program (ADP) under the Ministry of Health and Long-Term Care. Its mandate is to provide consumer centered support and funding to Ontario residents who have long-term physical disabilities to provide access to personalized assistive devices appropriate for the individual's basic needs. Its goal is to provide funding assistance for the rental of appropriate home oxygen equipment and supplies in order to correct or minimize hypoxemia resulting in improved health and increased participation in activities of daily living. (Home Oxygen Therapy - Policy and Administration Manual, Assistive Devices Program, Ministry of Health and Long-Term Care, Page 7, April 2014)

Note: It is the intent of the CPSO, Independent Health Facilities program to provide technical guidance on exercise testing for hypoxemia based on "Home Oxygen Therapy - Policy and Administration Manual, April 2014". The Facility must stay current with any updates and revisions published by Assistive Devices Program, Ministry of Health and Long-Term Care, Ontario.

Medical Eligibility Criteria for home oxygen:

- Chronic hypoxemia at rest, on room air:
 - Age ≥ 19: PaO₂ ≤ 55 mmHg or SaO₂ ≤ 88%
 - Age ≤ 18: SpO₂ ≤ 88%
- Persistent PaO₂ (56-60 mmHg) or SaO₂ (89-90%) on room air with any one of the following conditions:
 - Cor pulmonale
 - Pulmonary Hypertension
 - Persistent Erythrocytosis (polycythemia)
 - Exercise limited by hypoxemia and documented to improve with supplemental Oxygen
 - Nocturnal hypoxemia

Medical Eligibility Criteria for Hypoxemia on Exercise (Home Oxygen Program - Policy and Administration Manual, Assistive Devices Program, Ministry of Health and Long-Term Care, April 2014)

- Hypoxemia on exercise is defined as exertional saturation less than or equal to 88%.
- Funding for individuals who exhibit Hypoxemia on exercise is available only to:
 - those with hypoxemia on exercise whose exercise tolerance is restricted due to severe breathlessness and for those who are motivated to improve their daily activity level using oxygen therapy. Severe breathlessness is defined as Grade 4 or greater on the Medical Resource Council Dyspnea Scale (see Canadian Thoracic Society COPD Guidelines)
 - those who do not qualify under the Medical Eligibility Criteria for Hypoxemia at rest. Documentation of non-hypoxemia at rest may include ABG or resting Oximetry Study.
 - those with $SpO_2 < 80\%$ on walking with oxygen, regardless of dyspnea or distance walked
 - those with improved exercise tolerance with oxygen defined as one of the following:
 - c. $SpO_2 \leq 88\%$ on walking for five (5) minutes or more on room air, increase walked distance by 25% on oxygen along with an improvement of at least one unit in the Borg score at the end-exercise point of the shortest test
 - d. $SpO_2 \leq 88\%$ on walking for less than five (5) minutes on room air, increase walked time by a minimum of two (2) minutes on oxygen along with an improvement of at least one unit in Borg score at end-exercise point of the shortest test.

23.2 Prerequisites

Oxygen saturation at rest on room air:

Age ≥ 19 : $PaO_2 > 55$ mmHg or $SaO_2 > 88\%$ or $SpO_2 \geq 88\%$

Age ≤ 18 : $SpO_2 > 88\%$

Facility Requirements

- A 30 m-long, unobstructed (clear of obstacles and traffic) and straight-line walking course must be available
- The walking course should be marked at 3-meter intervals
- Orange traffic cones should be placed at the starting (0-meter) and 30-meter turnaround points
- Testing should be performed in a location where a rapid, appropriate response to an emergency is possible.
- The appropriate location of a crash cart should be determined by the physician supervising the facility.
- Supplies that must be available include oxygen, sublingual nitroglycerine, aspirin, and salbutamol (metered dose inhaler or nebulizer). A telephone or other means should be in place to enable a call for help.

23.3 Indications

- Shortness of breath on exertion with Grade 4 or higher on the MRC Dyspnea Scale
- Suspected exercise-related O₂ desaturation
- Interstitial lung disease
- COPD
- Other chronic lung diseases

23.4 Contra-Indications

23.4.1 Absolute:

- unstable angina during the previous month
- myocardial infarction during the previous month

23.4.2 Relative:

- resting heart rate of more than 120,
- systolic blood pressure of more than 180 mm Hg,
- diastolic blood pressure of more than 100 mm Hg.

Patients with any of these findings should be referred to the physician ordering or supervising the test for individual clinical assessment and a decision about the conduct of the test. The results from a resting electrocardiogram done during the previous 6 months should also be reviewed before testing. Stable exertional angina is not an absolute contraindication for a 6MWT, but patients with these symptoms should perform the test after using their anti-angina medication, and rescue nitrate medication should be readily available.

23.5 Indications for Test Termination

- chest pain
- intolerable dyspnea
- leg cramps
- staggering
- diaphoresis (sweating)
- pale or ashen appearance

23.6 Instrumentation and Supplies

- Oximeter
- Countdown timer (or stopwatch)
- Lap counter (mechanical or counter on worksheet)
- Two small orange cones to mark the turnaround points
- A chair or wheelchair for patient to sit in an emergency
- Worksheets on a clipboard

- A source of oxygen with nasal cannula
- Small tank of compressed air with flow meter
- Small tank of oxygen with flow meter
- Sphygmomanometer and stethoscope

23.7 Techniques and Measurements

Pre-Test Procedures

- Physicians are not required to be present during all tests. However, the supervising laboratory physician may decide whether physician attendance at a specific test is required.
- Comfortable clothing with walking shoes (sneakers)
- Patients should use their usual walking aids during the test (cane, walker, rollator etc.)
- Patients should take their medications as usual
- No meals and no vigorous exercise within 2 hours before test
- Patients should not wear nail polish or artificial acrylic nails
- Height and weight must be accurately measured

23.8 Test Procedures

- Patient should rest for at least 10 minutes in a chair near the starting point.
- During the 10 minutes rest, attach the oximeter probe to ensure that the SpO₂ and heart rate (or pulse rate) signals are acceptable and optimal and nasal cannula with compressed air set at 4 L/min. Since HOP prefers the study to be single-blinded, the technologist **should not** tell the patient he/she is receiving the compressed air. Instead, the technologist should tell the patient he/she is receiving a different level of oxygen. Some labs cover the compressed air tank to avoid patient recognition that the tank is compressed air. Compressed air can be mounted on a rollator or a light weight wheeled oxygen cart.
- Using the Worksheet (*see pg 49*), record at least the last 5 minutes of SpO₂ and heart rate readings.
- While standing at rest at the starting point, rate and record patient's dyspnea (shortness of breath) level using the Borg Scale (*see pg 162*).
- Patients should use their usual walking aids during the test (cane, walker, rollator etc)
- Do not walk with the patient unless patient is a fall risk even with the walking aids.
- Do not talk to anyone other than the patient during the walk.
- Watch the patient and do not get distracted and lose count of the laps.
- Keep conversation to the minimum. Use an even tone of voice to communicate with the patient for concerns or words of encouragement.
- Record the SpO₂ and heart rate at a periodic time interval (e.g.: 30 seconds interval) and when every lap is completed.
- Patient is allowed to rest if needed to and resume walking as soon as patient is able to continue (number of rests are recorded).

Note: Do not tell the patient he/she is receiving the compressed air. Instead, tell the patient he/she is receiving a different level of oxygen.

Patient walked for 6 minutes and SpO₂ > 88% with compressed air

- At the end of 6 minute mark, stop the patient and note the distance of the partial lap walked in meters. Rate and record patient's dyspnea level using the Borg Scale immediately.
- Ask the patient to sit and rest in a chair for recovery; continue to monitor the SpO₂ and heart rate for 2 minutes. If the 2-minute post walk SpO₂ and heart rate are returning close to the pre walk values, remove oximeter probe and patient can be discharged.

Patient walked less than five (5) minutes and SpO₂ ≤ 88% with compressed air

- Patient is stopped whenever a sustained SpO₂ is equal to or less than 88% whichever comes first, Record the time walked, rate and record patient's dyspnea level. A sustained SpO₂ value is reached when the same value is displayed and recorded twice at a sampling rate of 30-second intervals.
- Switch the compressed air to 100% oxygen cylinder and set the flow rate at 4 L/min and allow patient to breathe the oxygen for at least 10 minutes.
- Once the patient is rested enough and ready to repeat the walk test, record at least five (5) minutes of resting SpO₂ and heart rate. Record the resting Borg Scale while standing at the starting line just before patient starts walking
- The patient should walk an extra two (2) minutes from the time walked with compressed air. Borg Scale should be obtained while patient is still walking, at the same time when he/she stopped with compressed air.

Note: After setting the O₂ flow rate to 4 L/min, allow the patient to breathe the oxygen for at least 10 minutes before repeating the test.

Patient walked five (5) minutes and more and SpO₂ ≤ 88% with compressed air

- Patient is stopped whenever a sustained SpO₂ is equal to or less than 88% whichever comes first. Record the time walked, rate and record patient's dyspnea level. A sustained SpO₂ value is reached when the same value is displayed and recorded twice at a sampling rate of 30-second intervals.
- Switch the compressed air to 100% oxygen cylinder and set the flow rate at 4 L/min and allow patient to breathe the oxygen for at least 10 minutes.
- Once the patient is rested enough and ready to repeat the walk test, record at least five (5) minutes of resting SpO₂ and heart rate. Record the resting Borg Scale while standing at the starting line just before patient starts walking
- The patient should walk an additional 25% of the distance walked with compressed air. Borg Scale should be obtained while patient is still walking, at the same time when he/she stopped with compressed air.

Calculations:

- Calculate the distance walked from adding the total laps walked multiply the distance per lap (e.g. 30 meters) and the partial distance walked in meters at the end of the walk.

23.9 Reporting Guidelines

- See pg 166 Sample Exercise Oximetry Report
- Resting SpO₂ must be recorded with a minimum of 10 minutes rest.
- When switching from room air to supplemental oxygen or vice and versa, a minimum of 10 minutes should elapse before starting the walk test.
- Resting Borg Scale should be rated and recorded while standing.
- Report the low and high values (range) of SpO₂ and Heart Rate for the duration of the walk test
- Calculate the walk distance.
- Compare the walk distance against predicted 6MWD, Lower Limit of Normal and percent predicted.

Note: Home Oxygen Assessment protocol for exercise duration is not limited to "six (6) minutes", the interpreting physician must interpret percent predicated accordingly when the walking time exceeds six (6) minutes.

23.10 Interpretation

Interpreting physician must familiar with the current protocol and eligibility criteria set by the Home Oxygen Program, Assistive Devices Program, Ministry of Health and Long-Term Care (see Fig. 1 Flow Chart for Exercise Oximetry for Home Oxygen Assessment).

Fig. 1 Flow Chart for Exercise Oximetry for Home Oxygen Assessment

Exercise Oximetry for Home O₂ Assessment

(Assistive Devices Program, MOH, April 2014)

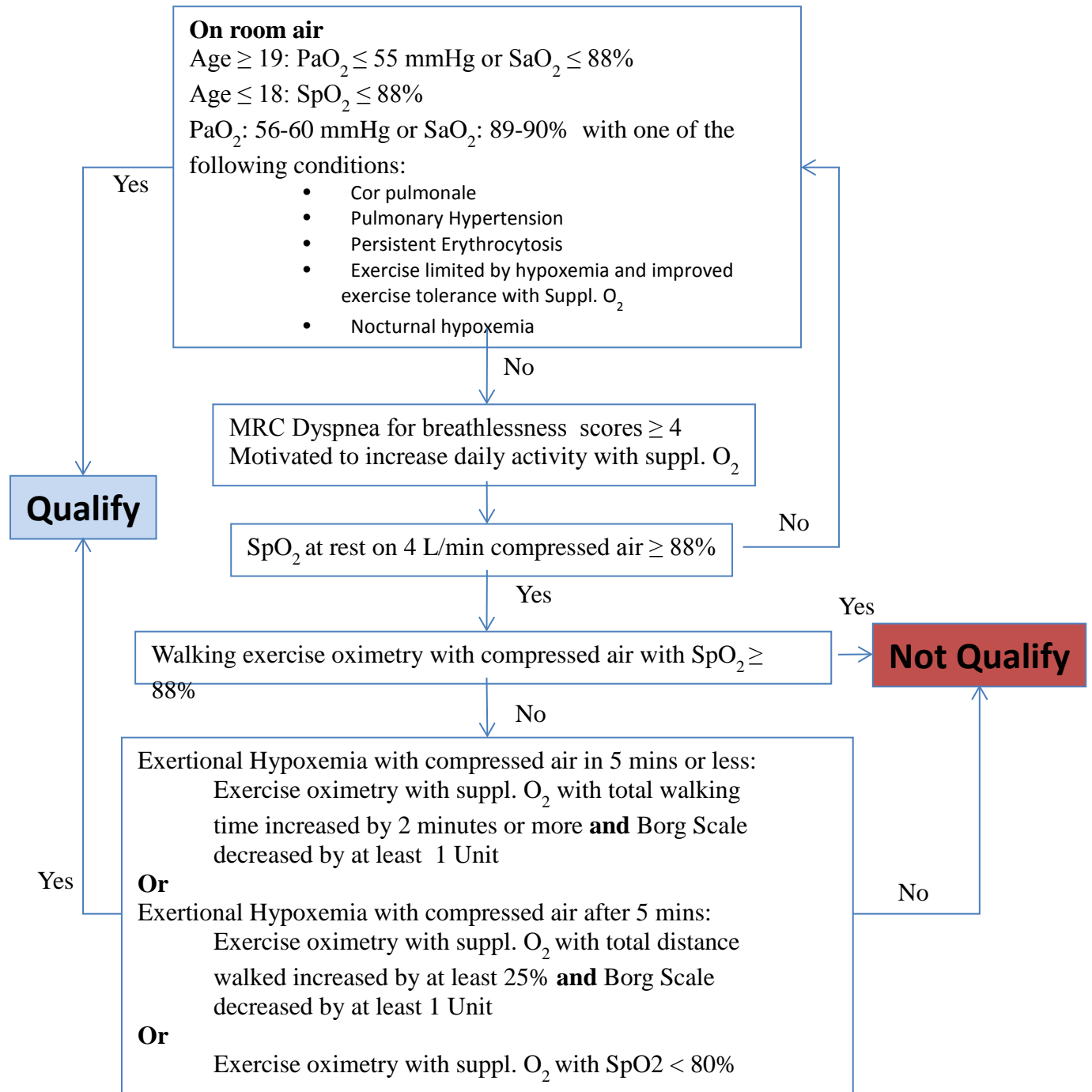


Fig. 2 Borg Scale

Dyspnea Grade

Please grade your level of shortness of breath from 0 – 10 using the scale below

Borg Scale

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

Fig. 3 Exercise Oximetry Worksheet

6-MWT
 Room Air Supplemental O2 ____ L/min (%) Nasal Prongs Mask
 Home O2 Assessment
 Compressed air (4L/min) Supplemental O2 (4L/min) Nasal Prongs Mask

	Activity	Timer (m:s)	SpO2 (%)	Pulse Rate (HR, b/m)	Lap Counter (1 Lap = 30 meters)	
Borg Scale Rest (Standing)	Rest (Sitting)	8:00			1	16
	Rest (Standing)	9:00			2	17
	Standing	9:30			3	18
	Standing	10:00			4	19
	WALK	0:30			5	20
	Borg Scale Exercise	↓	1:00			6
		1:30			7	22
		2:00			8	23
		2:30			9	24
		3:00			10	25
		3:30			11	26
		4:00			12	27
		4:30			13	28
		5:00			14	29
		5:30			15	30
	STOP	6:00				
	RECOVERY	7:00				
		7:30				
		8:00				
Rest Counter: 1 2 3 4 5 6 7 8 9 10					+	M
Tech comments: Walked with <input type="checkbox"/> cane <input type="checkbox"/> walker <input type="checkbox"/> rollator					Total Distance Walked = #Lap ____ *30 + ____ meters = ____ meters	

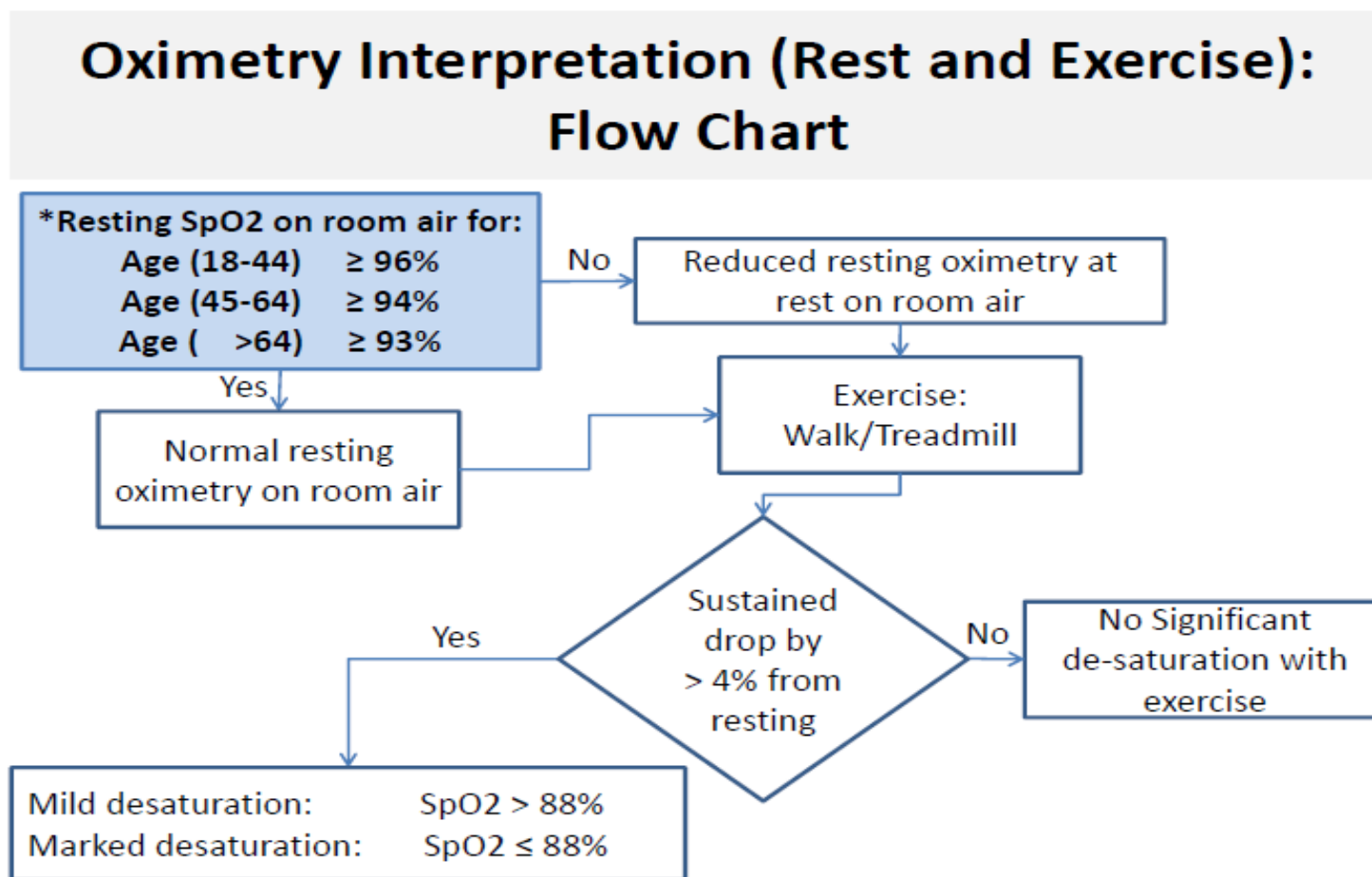
Fig. 4 Sample of Exercise Oximetry Report

6-MWT
 Room Air Supplemental O₂ ____ L/min (%) Nasal Prongs Mask
 Home O₂ Assessment
 Compressed air (4L/min) Supplemental O₂ (4L/min) Nasal Prongs Mask

	Level 1	Level 2
Inspired supplemental O ₂ (L/min)		
Rest SpO ₂ (%)		
HR (b/min)		
Borg Scale (0-10)		
Exercise SpO ₂ (range: high – low)		
HR (range: low – high)		
Borg Scale (0-10)		
Distance Walked (meters)		
Distance Predicted (meters)		
Distance % Predicted		
Distance (Lower Limit of Normal)		
Total Time Walked (m:s)		
% Change from Level 1		
Number of Rests		

Tech comments: Walked with <input type="checkbox"/> cane <input type="checkbox"/> walker <input type="checkbox"/> rollator
Physician Interpretation:

Fig. 5 Oximetry Interpretation (Rest and Exercise): Flow Chart



* Crapo, RO et al. Arterial Blood Gas Values for sea level and an Altitude of 1400 meters. Am J Respir Crit Care Med 1999; 160: 1525-1531
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APPENDICES

Appendix I Independent Health Facilities Act - Ontario Regulation 57/92

Note: Ontario Regulation 57/92 has previously been amended. Those amendments are listed in the Table of Regulations - Legislative History Overview which can be found at www.e-laws.gov.on.ca. Facilities are encouraged to check the Government Website for updates.

Quality Advisor and Advisory Committee

1(1) Every licensee shall appoint a quality advisor to advise the licensee with respect to the quality and standards of services provided in the independent health facility.

(2) If the quality advisor dies or ceases to be the quality advisor, the licensee shall appoint a new quality advisor forthwith.

(3) The quality advisor must be a health professional who ordinarily provides insured services in or in connection with the independent health facility and whose training enables him or her to advise the licensee with respect to the quality and standards of services provided in the facility.

(4) It is a condition of a licence that the quality advisor be a physician if all the insured services provided in the independent health facility that support the facility fees that the licensee may charge are provided by physicians.

(5) In subsection (4), an insured service supports a facility fee if the facility fee is for or in respect of a service or operating cost that supports, assists or is a necessary adjunct to the insured service.

(6) A licensee who is qualified under subsection (3) may appoint himself or herself as the quality advisor only if there is no other health professional who is qualified to be the quality advisor who will consent to be the quality advisor. O. Reg 57/92, s.1.

2(1) Every licensee shall appoint an advisory committee to advise the quality advisor.

(2) The advisory committee shall consist of health professionals who provide health services in or in connection with the independent health facility.

(3) The quality advisor shall be the chair of the advisory committee.

(4) Every licensee shall use his or her best efforts to ensure that there is a representative on the advisory committee from the health profession and each specialty and sub-specialty of medicine, practitioners of which provide health services in or in connection with the independent health facility. O.Reg. 57/92, s.2.

3(1) Every licensee shall give the Director the name of the quality advisor in writing forthwith after the quality advisor is appointed.

(2) If the quality advisor dies or ceases to be the quality advisor, the licensee shall inform the Director in writing forthwith.

(3) Every licensee shall give the Director, on request, the names of the members of the advisory committee in writing. O. Reg. 57/92, s.3.

Standards

4 (1) Every licensee shall ensure that all aspects of the services provided in the independent health facility are provided in accordance with generally accepted professional standards.

(2) Every licensee shall ensure that the persons who provide services in the independent health facility are qualified, according to generally accepted professional standards, to provide those services.

(3) If the quality advisor has reasonable grounds to believe that this section is not being complied with, he or she shall inform the Director forthwith. O. Reg. 57/92, s.4.

5 Every licensee shall keep a system to monitor the results of the services provided in the independent health facility. O. Reg. 57/92, s.5.

6(1) Every licensee shall ensure that all tissues removed from a patient during an operation or curettage performed in an independent health facility are sent to a laboratory for examination and report unless the physician performing the operation or curettage is of the opinion that it is not necessary according to generally accepted medical standards.

(2) The licensee shall ensure that a short history of the case and a statement of the findings of the operation or curettage are sent with the tissues. O. Reg. 57/92, s.6.

Records of Employees

7 (1) Every licensee of an independent health facility shall maintain, for each employee of the facility who is not a physician, an employment record setting out the employee's qualifications and employment history including a record of any registration with or licensing by the governing body of a health profession.

(2) Every licensee shall retain an employee's employment record for at least two years after the employee ceases to be an employee. O. Reg. 57/92, s.7.

8 (1) Every licensee of an independent health facility shall maintain a record of qualifications and work history for:

(A) each person the licensee contracts with to manage the facility; and

(B) each person who is not a physician who the licensee contracts with to provide patient-related services in the facility.

(2) The record shall include a record of any registration with or licensing by the governing body of a health profession.

(3) Every licensee shall retain the record for a person the licensee contracts with for at least two years after the licensee ceases to contract with the person. O. Reg. 57/92, s.8.

9 (1) Every licensee shall maintain a declaration of professional standing for each physician who provides professional services in the independent health facility.

(2) A declaration of professional standing must include the following information:

1. The physician's name
2. The physician's registration number with the College of Physicians and Surgeons of Ontario
3. The physician's number registered with the Health Insurance Division of the Ministry of Health.
4. The class of the physician's licence issued under Part III of the Health Disciplines Act and any terms and conditions attached to it.
5. The physician's specialty.

(3) Every licensee shall give the Director a copy of each declaration of professional standing, forthwith after the obligation to maintain it begins under subsection (1).

(4) Every licensee shall give the Director a written statement of any change in a declaration of professional standing forthwith after the change.

(5) Subsections (3) and (4) do not apply with respect to physicians providing services on a temporary basis for less than twelve weeks. O.Reg. 57/92, s.9.

Patient Records

10 (1) Every licensee of an independent health facility shall keep, for each person who is or was a patient, a health record relating to the health services provided in the facility.

(2) A patient's health record must include:

- (a) the patient's name and home address
- (b) the patient's date of birth
- (c) the patient's health number
- (d) the name of any attending physician or practitioner and his or her number as registered with the Health Insurance Division of the Ministry of Health
- (e) the name of any referring physician or practitioner and his or her number as registered with the Health Insurance Division of the Ministry of Health
- (f) a history of the patient
- (g) a written record of any orders for examinations, tests, consultations or treatments
- (h) particulars of any examination of the patient
- (i) any reports of examinations, tests or consultations including any imaging media from examinations and any physicians' interpretive or operative reports

- (j) any reports of treatment including any physicians' operative reports
- (k) any orders for and reports of any discharge of the patient from supervised care
- (l) any consents; and
- (m) any diagnoses of the patient.

(3A) patient's health record need not contain a history of the patient if the patient came to the independent health facility for diagnostic services only and received on such service.

(4) Every licensee shall ensure that every part of a patient's record has a reference on it identifying the patient or the record.

(5) If information in a patient's record is kept in the form of a chart, each entry in the chart must be dated and it must be initialled by the person authorizing the entry. O.Reg. 57/92, s.10.

11 (1) Every licensee shall retain a patient's health record or a copy of it for at least six years following:

- (a) the patient's last visit; or
- (b) if the patient was less than eighteen years old when he or she last visited the facility, the day the patient became or would have become eighteen years old.

(2) Despite subsection (1), a licensee is not required to retain imaging media from any examination other than a mammography for more than three years following:

- (a) the patient's last visit; or
- (b) if the patient was less than eighteen years old when he or she last visited the facility, the day the patient became or would have become eighteen years old.

(3) Every licensee shall retain the film from a mammography for at least ten years following the patient's last visit. O.Reg. 57/92, s.11.

(4) On the transfer of a licence under section 11 of the Act, the transferor of the licence shall transfer to the transferee of the licence, in a manner that will protect the privacy of the records, the records maintained under section 10 of this Regulation, and the transferee of the licence shall retain those records in accordance with this section.

Section 12 of the Regulation is revoked and the following substituted:

12 (1) No licensee shall allow any person to have access to any information concerning a patient that is not subject to the Personal Health Information Protection Act, 2004 except in accordance with subsection (3).

(2) The reference to "information concerning a patient" in subsection (1) includes information or copies from a health record, even if anything that could identify the patient is removed.

(3A) A licensee may provide information described in subsection (1) to the following persons if anything that could identify the patient is removed from the information:

1. Any person, if the information is to be used for health administration or planning or health research or epidemiological studies and the use is in the public interest as determined by the Minister.

2. Cancer Care Ontario. O Reg. 346/04, s.2.

Books and Accounts

12.1(1) This section applies to licensees of independent health facilities that are funded under section 24 of the Act, other than independent health facilities whose funding is based solely on the Ministry of Health publication titled "Schedule of Facility Fees".

(2) Every licensee shall keep the following records in relation to the independent health facility:

1. Current financial records showing:

(i) the amounts paid by the Minister to the licensee under section 24 of the Act.

(ii) the revenue earned by the licensee from facility fees charged by the licensee for or in respect of services or operating costs that support, assist or are a necessary adjunct to the primary insured services set out in the licensee's licence, and

(iii) the expenditures, assets and liabilities of the facility that relate to the costs paid by the Minister under section 24 of the Act.

2. A reporting record listing each service provided in the facility that is a primary insured service set out in the licensee's licence and each service provided in the facility that is a funded service under section 24 of the Act and showing how many of each of such services are provided.

3. An annual income and expense statement showing the income received and the expenses incurred by the licensee in connection with the services mentioned in paragraph 2.

4. An annual inventory of the assets of the facility that have an acquisition cost exceeding \$3,500 and that relate to the costs paid by the Minister under section 24 of the Act.

(3) Every licensee shall ensure that the records required under section (2):

(a) are kept in the independent health facility; and

(b) are kept in a bound or loose-leaf book or are recorded by a system of mechanical or electronic data processing or any other information storage device.

(4) Every licensee shall ensure that any part of a record required under subsection (2) that relates to a period of time is retained for at least six years following the end of the period.

(5) Every licensee shall ensure that the accounts of the independent health facility are audited by a person licensed under the *Public Accountancy Act*. O.Reg. 283/94, s.1, part.

12.2 Every licensee of an independent health facility shall furnish such information and accounts as the Director may require. O. Reg. 283/ 94, s.1, part.

Notices

13 Every licensee of an independent health facility,

(a) who decides to cease operating the facility at a future date shall give the Director, as soon as possible, written notice of the date; and

(b) who ceases to operate the facility shall give the Director, within seven days after the date the licensee ceases to operate the facility, written notice of the date. O. Reg. 57/92, s.13.

14 Every licensee of an independent health facility shall give the Director:

(a) if the licensee is a corporation, written notice of any change in the location of the licensee's head office within ten days after the change; and

(b) written notice of any change in the name under which the licensee carries on business within ten days after the change. O.Reg. 57/ 92, s.14.

Miscellaneous

15 It is a condition of a licence that the licensee post the first page of the licence in a conspicuous place in the independent health facility. O. Reg. 57/92, s.15.

16(1) The fee for a licence is \$100.

(2) The fee for the transfer of a licence is \$100.

(3) The fee for the renewal of a licence is \$100. O. Reg. 57/92, s.16.

17 The administrative charge for the purposes of section 36 of the Act is \$50. O. Reg. 57/92, s.17.

Appendix II Sample Emergency Safety Policy

Safety Training for all staff should be carried out. In addition, an emergency safety policy should be included in the policies and procedures manual. This appendix has been provided as a sample of what the policy may look like and include. Each policy must be site specific to the facility and may include but is not limited to the following areas:

Employer Responsibilities (*in all incident cases*):

Provide first aid in accordance with the regulations.

Record first aid attention, adverse effects, incident report.

Assist to provide immediate transportation to the hospital, doctor, worker/patient's home, when/as necessary.

Employee Responsibilities

Acute Care Transfer

Should a patient, visitor, and/or staff become ill while in the clinic the following is carried out:

1. Immediately, the technologist or clerical staff will alert the attending Radiologist of the problem.
2. In the event that the attending Radiologist is not available, contact a local GP (agreement should be made prior between facility and physician – contact numbers should be available for staff).
3. If the physician is not immediately available, call 911, identify yourself and request transfer to the nearest hospital.

Fire Prevention and Control Plan

1. All staff members employed at the facility is required to know the fire plan. To facilitate this, an annual review of the plan will be carried out and is mandatory for all staff members.
2. The fire plan is site-specific for the facility. Staff members are required to familiarize themselves with the plan for this location.
3. Each employee should have the ability to assess the situation quickly and initiate appropriate measures upon discovering a fire. This may vary from using a fire extinguisher to contain a fire or alerting others, evacuating the building and calling the fire department.

If you discover a fire in your area:

1. Remove patients from rooms and out of danger.
2. Turn off lights, any electrical equipment, gases, and close windows and doors.
3. Pull the alarm located closest to you.
4. Dial 911 and advise the Fire Department of the Emergency. Give them your name, location of the fire and type of fire to the communications operator (electrical, gas, other).

5. If possible (i.e. the fire is contained to a specific area) go back to the room and attempt to put out the fire using a fire extinguisher.

DO NOT ATTEMPT TO USE THE FIRE HOSE. Everyone should be removed from the office. Have a staff member positioned at the main corridor junction to direct fire fighters.

If you hear a fire alarm:

1. Collect all patients, visitors, and staff members in the facility and guide them to the closest exits.
2. DO NOT USE THE ELEVATOR. All staff members along with anyone in the office at the time of the evacuation alarm, must meet at a predetermined assembly point outside of the building.
3. Personnel will be requested to assist with duties such as checking the office before leaving ensuring that everyone is accounted for, turning off lights in the fire area, turning off gases (oxygen), turning off all electrical equipment and closing doors and windows.

The First Aid Box

As a minimum the first aid box should contain:

- A current edition of a first aid manual
- One card of safety pins
- Dressings, consisting of:
 - 12 adhesive dressings, individually wrapped
 - 4 sterile gauze pads, 3 inches square
 - 2 rolls of gauze bandages, 2 inches wide

Appendix III Sample Requisition

Suggested Requirements for a Pulmonary Function Test Requisition Form

Facility Information:

Name, Address, Telephone and Fax numbers

Referring Physician Information:

Name, Address, Telephone and Fax numbers, Physician OHIP number and signature space.

Patient Information:

Name, Gender, Address, Telephone (Day/Home) and Fax numbers, DOB, OHIP Number with version code, preferred appointment day and time

Clinical Diagnosis:

List common respiratory diseases for physician to check off, e.g.: Asthma, COPD and a line space for manual entry.

Clinical Information:

List of common clinical information for physician to check off, e.g.: respiratory inhaler types, smoking history, current hemoglobin (within 3 months), previous M.I. and a line space for manual entry.

Reason For Test:

List of common reasons for physician to check off, e.g.: Diagnosis, Follow-up, Baseline measurement and a line space for manual entry.

Services (Tests) Provided:

List of tests available for physician to check off, e.g.: Spirometry, lung volumes, diffusion capacity, 6-minute walk test, home oxygen assessment, oxygen prescription

Request Status:

A check box for physician to check off the request status, e.g.: Urgent / Routine.

Patient Instruction for Test:

A sheet or pamphlet is available for patient to prepare for the required tests.

Sample of Requisition for Pulmonary Tests Form

<p>Requisition for Pulmonary Function Tests</p> <p>XYZ Pulmonary Function Laboratory 123 Any Street, Any Town, Ontario M1M 1M1</p> <p>Phone: (123) 456-7890 Fax: (123) 098-7654</p> <p>Request Status:</p> <p><input type="checkbox"/> [] Urgent <input type="checkbox"/> [] Routine</p>	<p>Patient Information:</p> <p>First/Last Name: _____</p> <p>Gender: [] M/ [] F Date of Birth: _____ yyyy/mm/dd</p> <p>Address: _____</p> <p>Phone (Day): _____ (Home): _____</p> <p>Fax: _____</p> <p>OHIP#: _____ Ver.Code: _____</p> <p>Preferred Day: _____ Time: [] AM [] PM</p>
<p>Referring Physician Information:</p> <p>First/Last Name: _____ Phone: _____ Fax: _____</p> <p>Address: _____</p> <p>Physician OHIP #: _____</p> <p style="text-align: right;">Signature – Date: yyyy/mm/dd</p>	
<p>Clinical Diagnosis: [<input type="checkbox"/>] Asthma [<input type="checkbox"/>] COPD [<input type="checkbox"/>] ILD [<input type="checkbox"/>] Other:</p>	
<p>Clinical Information: [<input type="checkbox"/>] Smoker [<input type="checkbox"/>] Ex-smoker _____ Pack Year [<input type="checkbox"/>] Life-time non-smoker</p> <p>Hgb: _____ g/L on _____ [<input type="checkbox"/>] Respiratory inhaler: _____ yyyy/mm/dd</p>	
<p>Reasons for tests: [<input type="checkbox"/>] Diagnosis [<input type="checkbox"/>] Follow-up [<input type="checkbox"/>] Baseline measurement [<input type="checkbox"/>] Other:</p>	
<p>Test(s) Requested: <i>(Note: In order to obtain reliable results, patient must be able to follow verbal instructions.)</i></p> <p>[<input type="checkbox"/>] Spirometry [<input type="checkbox"/>] Lung Volumes [<input type="checkbox"/>] Diffusion Capacity</p> <p>[<input type="checkbox"/>] All of the above</p> <p>[<input type="checkbox"/>] Post-bronchodilator Spirometry Challenge* (400 mcg Salbutamol)</p> <p>[<input type="checkbox"/>] Oxygen Saturation at rest</p> <p>[<input type="checkbox"/>] Methacholine Challenge Test*</p> <p>[<input type="checkbox"/>] 6-Minute Walk Test</p> <p>[<input type="checkbox"/>] Exercise Oximetry for Home Oxygen Assessment</p> <p>*Required special patient instruction to withhold certain respiratory medications.</p>	

Appendix IV Sample Patient Survey: Quality of Care

Note: Surveys must be site specific.

Please rate the following about your visit to this clinic in terms of whether they were poor, fair, good, very good, or excellent. Circle the number 1 for poor; 2 for fair; 3 for good; 4 for very good, and 5 if you felt it was excellent. If something doesn't apply to your visit or you don't have an opinion, please circle the number 8.

<i>Please rate each by circling the number that best describes your opinion</i>	Poor	Fair	Good	Very Good	Excellent	Not Applicable No Opinion
1. Waiting time: how long you had to wait to get an appointment at this clinic	1	2	3	4	5	8
2. Waiting time: how long you had to wait in the clinic waiting room for your appointment	1	2	3	4	5	8
3. Instructions: how well the clinic staff (doctors, receptionists, technologists etc.) told you how to prepare for the test(s) and what to expect both before and/or during the test(s)	1	2	3	4	5	8
4. Ease of getting information: willingness of clinic staff to answer your questions	1	2	3	4	5	8
5. Information you were given: how clear and complete the explanations were about any possible risks and complications of the test(s)	1	2	3	4	5	8
6. Concern and caring by clinic staff: courtesy and respect you were given, friendliness and kindness; how well clinic staff listened to what you had to say; how well the clinic staff understood what you thought was important	1	2	3	4	5	8
7. Safety and security: the provisions for your safety and the security of your belongings	1	2	3	4	5	8
8. Privacy: how well your privacy was considered, for example, type of gowns used, privacy while changing clothes	1	2	3	4	5	8
9. Instructions on leaving: how clearly and completely you were told what to do and what to expect when you left the clinic	1	2	3	4	5	8

<i>Please answer the following questions by circling 1 for Yes or 2 for No.</i>					YES	NO
10. Were you told to leave the clinic before you felt ready to do so?					1	2
11. Did you have to visit a physician, walk-in clinic, emergency room, urgent care centre or hospital in the days following this service because your health got worse as a result of the service(s) received at the clinic?					1	2
12. Would you recommend the clinic to a friend or family member if they needed services that it provides?					1	2
<i>Please rate this item by circling the number that best describes your opinion</i>	Poor	Fair	Good	Very Good	Excellent	Not Applicable No Opinion
13. Overall quality of care: how you evaluate the services you received and the way you were treated	1	2	3	4	5	8
14. If there were some things you could change about this visit to improve it, what would they be?						

Thank you for completing this survey. Please double check that you have answered all questions and then place the survey in the envelope provided. Your answers will be kept completely confidential.

Thank you again for your help!

Appendix V Sample Referring Physician Survey

Note: Surveys must be site specific.

Name of facility _____

Please answer the following questions regarding your experience with the above facility by filling in the blank or circling the number that best describes your answer.

1. How long have you referred patients to this facility?

_____ years or _____ months

Please base your answers on your contact with the facility in the past 6 months.

2. How satisfied are you with how long it generally takes: (Please rate each item by circling the number that best describes your opinion)

3. How often do you speak to a physician at the IHF regarding the patient's clinical condition before your patient receives a diagnostic work-up?

Never Rarely Occasionally Sometimes Often Almost all the time

4. Approximately how many patients have you referred to this facility in the past 6 months? _____ (number of patients referred)

5. Do you refer your patients to more than one facility of this type?

A. No (*if you circled No, please skip to Question number 7*) B. Yes

6. What are the reasons you refer patients to this particular facility? (Please circle all that apply.)

- a. Nearer Patient's home
- b. Has specialized equipment needed for test requested
- c. Turnaround time to receive the results is shortest
- d. Has staff that speak other languages, and thus can better understand my patients
- e. Is able to quickly see patients when feedback is urgently required
- f. Has convenient hours of operation
- g. Quality of the services provided
- h. Other, please describe _____

7. What are the reasons you refer patients only to this facility? (Please circle all that apply.)

- a. Only facility of its type in this community
- b. Our group has a service contract with this facility
- c. Facility is located near this practice and is thus convenient for patients
- d. Has staff that speak other languages and thus can better understand my patients
- e. Has specialized equipment needed for tests requested
- f. Turn-around time to receive results is short
- g. Nearest patients' homes
- h. Is able to quickly see patients when feedback is urgently required
- i. Quality of the services provided
- j. Has convenient hours of operation
- k. Other, please describe _____

8. Have you been dissatisfied with a consult you received from this facility in the past six months?

- a. No
- b. Yes

9. Please rate each item by circling the number that best describes your experience with the IHF based on your contacts in the last 6 months.

	Never	Seldom	Sometimes	Frequently	Usually
The waiting period for a test to be done is long.	1	2	3	4	5
Requests for consultation are handled promptly.	1	2	3	4	5
The facility accommodates patients when the test is urgently required.	1	2	3	4	5
The interpreting physician is available to you for consultation.	1	2	3	4	5
This facility meets the needs of my patients whose first language is other than English or French.	1	2	3	4	5
The recommendations received are useful in patient management.	1	2	3	4	5
The recommendations are clearly stated.	1	2	3	4	5

The reports received are too wordy.	1	2	3	4	5
Reports of results are sent out in a timely fashion.	1	2	3	4	5
The consulting physician orders tests in addition to those you requested.	1	2	3	4	5
When tests are added the resulting recommendations add information important to patient care.	1	2	3	4	5
The interpreting physician's findings are generally consistent with your clinical findings.	1	2	3	4	5

If 2 (Yes), please explain: _____

10. **Overall, how satisfied are you with the contacts you have had with this facility in the past six months?**

- Very Dissatisfied b. Dissatisfied c. Neutral d. Satisfied e. Very Satisfied

Thank you for participating in this survey. Please return the survey in the envelope provided.

Our address is:

Appendix VI Sample Patient Prep Instructions

Overview

Your doctor has requested a Pulmonary Function Test for you. If your doctor gave you the Requisition form and asked you to make the appointment by yourself, please phone our Laboratory with the following information ready.

- Patient's name, Date of birth and Health Card Number, Home Address and Telephone number
- Test(s) requested on the Requisition

You may fax the Requisition to us with your daytime phone number. We will call you back with the appointment date and time. You **MUST** bring the original Requisition and Health card on the day of your appointment

General Preparations

- Fasting is not required, but avoid eating a heavy meal at least 2 hours before test.
- Avoid exercise within one hour of test starting time.
- Wear loose comfortable clothing.
- Do not smoke on the day of the test.
- Do not consume alcohol within 4 hours of testing start time.
- If you are unable to follow verbal instruction in English, come with your own interpreter.
- Postpone this test if you have a flu, fever, severe headache or diarrhea.
- If you are unable to keep the appointment, please call the Laboratory at **(XXX) XXX-XXXX** immediately.
- Please **ARRIVE** for your appointment on time. ***(Your test may be delayed or re-scheduled for late arrival)***

What is a Pulmonary Function Test?

The Pulmonary Function Test, also commonly known as a Breathing Test, is designed to measure how well your lungs are working. You will be asked to breathe in and out through different machines, just as if you were blowing up a large balloon or blowing out a dozen candles all in one breath. The results will provide an objective assessment of your lung functions to your doctor, to confirm or rule out a diagnosis, to evaluate effectiveness of current treatment or other information. A complete test usually takes about **ONE HOUR** plus any addition test your doctor requested.

Pulmonary Function Test includes one or any combination of the following:

- Spirometry with or without use of a bronchodilator

- Lung Volumes, Diffusion Capacity
- Respiratory Muscle Strength
- Methacholine Challenge
- Exercise Oximetry
- Exercise-induced Bronchoconstriction

Spirometry with or without Bronchodilator (15-30 mins)

You will be asked to blow into a machine as fast and as hard as you possibly can.

Your doctor may want to know whether a puffer (bronchodilator) helps your breathing, especially if this is your first time. **Unless you received a specific instruction from your doctor and your breathing condition is able, you should not take any bronchodilator medication before the test: 4 hrs for Ventolin and Atrovent, etc; 12 hrs for Symbicort, Advair and Spiriva, etc.** This test will take about 15 minutes (30 minutes if before and after bronchodilator testing is requested). Please talk to your doctor or call our Laboratory if you have any concerns.

Lung Volumes (10-20 mins)

This is a test to measure the size of your lungs.

Diffusing Capacity (10-15mins)

This is a test to measure how fast oxygen gets into your blood. You will be asked to breathe in a test gas and hold your breath for about 7 seconds and then blow out the gas from your lungs for analysis. This test is sensitive to carbon monoxide in your lungs; you should not smoke at least 4 hours before the test.

Respiratory Muscle Strength (10 mins)

This is a test to measure the strength or power of your breathing muscles. You will be asked to blow out or breathe in as hard as you can against a blockage.

Methacholine Challenge Test (30-60 mins)

This is a test to measure the sensitivity of the airways by inhaling different concentrations of Methacholine Mist. If you develop chest tightness or coughing, you will be given a puffer to relieve the symptoms. The puffer (a bronchodilator) works quickly to provide relief.

The test is designed to assess the sensitivity of your airways. You will be asked to inhale a mist that contains different concentrations of methacholine solution. The mist is produced by a device called nebulizer and inhaled through a mouthpiece for 2 minutes. Before the test begins and after each period of inhalation, you will be asked to blow forcefully into a spirometer to measure the effect of the Methacholine on your airways. The test usually takes about an hour.

Stop for 3 days before Test

- Antihistamine
- Dimenhydrinate (Gravol)
- Hydroxazine (Atarax)
- Cetirizine (Reactine), etc.

BETA-BLOCKER MEDICATION

Please inform the Laboratory if you are taking the following beta-blocker medication to control your high blood pressure.

- Atenol-APO (Atenolol)
- Betaloc (Metoprolol tartrate)
- Brevibloc (Esmolol HCl)
- Lopresor (Metoprolol tartrate)
- Monacor (Bisoprolol fumarate)
- Nadol-APO (Nadolol)
- Propanolol-APO (Propranolol HCl)
- Sectral (Acebutolol HCl)
- Slow-Trasicor (Oxprenolol HCl)
- Timol-APO (Timolol maleate)
- Transdate (Labetalol HCl)
- Visken (Pindolol)

General Preparations

DO

- have light meal two (2) hours before test if needed
- wear comfortable clothing
- bring English speaking interpreter if necessary
- postpone this test if you are pregnant or breastfeeding, please discuss with your doctor
- inform the Laboratory if you are unable to stop taking beta-blocker (see Beta-Blocker below) for 24 hours.
- re-schedule this appointment if you have a cold or a flu

DO NOT

- smoke on the day of the test.
- exercise on the day of test.
- take breathing medications that may affect the test sensitivities (see “Stop Medications” below).

Stop Medications

Certain medications will interfere with the result of this test. Therefore, you should stop these medications for the period of time indicated on the table below. If you have any concern about stopping the medication, you should discuss with your doctor or phone the Laboratory for further information.

Table of withholding respiratory medications for Methacholine Inhalation Challenge and Exercise-Induced Broncho-constriction.

Duration of withholding	Medication Class	Examples
6 hours	Short-acting inhaled beta agonists or Short-Acting Beta2 Agonist (SABA)	Salbutamol (Airomir, Bricanyl, Ventolin)
12 hours	Short-acting anticholinergics or Short-Acting Muscarinic Antagonist (SAMA)	Ipratropium (Atrovent)
36 hours	Long-acting inhaled beta agonists or Long-Acting Beta2 Agonist (LABA)	Formoterol (Foradil, Oxeze, Symbicort, Zenhale) Salmeterol (Advair, Serevent)
48 hours	Ultra-long-acting beta agonists or Ultra LABA	Indacaterol (Onbrez Breezhaler) Olodaterol (Striverdi Respimat) Vilanterol (Breo Ellipta)
168 hours (7 days)	Long-acting anticholinergics or Long-acting Muscarinic Antagonist (LAMA)	Aclidinium (Tudorza Genuair) Glycopyrronium (Seebri Breezhaler) Tiotropium (Inspiroto Respimat, Spiriva) Umeclidinium (Incruse Ellipta)
12-24 hours	Methylxanthines	Oral Theophylline

Exercise Oximetry (20-45 mins)

This test is to measure your exercise capacity and oxygen level while you are walking on the treadmill or walking in the hallway. You may be asked to see how far you can walk in 6 minutes. Wear suitable clothing and shoes for exercise and do not wear nail polish.

Exercise-Induced Bronchoconstriction (45 mins)

This test is to measure your breathing before and after fast running on the treadmill for 6 minutes while your heart rate and oxygen level are monitored. Wear suitable clothing and shoes for exercise. Do not wear nail polish. **Do not do any exercise on the day of your appointment. Do not take respiratory medications under the Stop Medication Table of the Methacholine Challenge Test above.** A bronchodilator puffer will be given to you if you feel your chest feels tight after the exercise.

Appendix VII Sample Methacholine Challenge Test Consent Form

(Modified from Appendix C of [2017 ERS technical standard on bronchial challenge testing: general considerations and performance of methacholine challenge tests](#))

PROCEDURE:

There are many conditions that may cause cough and wheezing or shortness of breath, asthma being one of the most common. Methacholine challenge tests can be very useful in determining if the symptoms you or your child are having are due to asthma or are due to some other lung problem. The purpose of a methacholine challenge test is to determine if you or your child's airways constrict abnormally when a small amount of irritant is inhaled. You (or your child) will be asked to inhale a mist that contains different concentrations of a medication called methacholine. The mist is produced by a device called a nebulizer and inhaled through a mouthpiece. Before the test begins, and after each period of inhalation, you or your child will be asked to blow forcefully into a spirometer, a device that measures how much air you can blow out and how fast. The results from the test can help your doctor to decide which treatments are likely to work best for you or your child. The test usually takes about an hour.

DISCOMFORTS AND RISKS:

This test does not cause an asthma attack but the inhalation of aerosols may be associated with irritation and constriction of the airways with mild shortness of breath, cough, chest tightness, wheezing, chest soreness, or headache. Many people do not have any symptoms at all. These symptoms (if they occur) are normally mild, last for only a few minutes, and disappear following the inhalation of a bronchodilator which is routinely administered and which causes the airways to relax. There is a very small possibility of severe narrowing of your airways. This could cause severe shortness of breath. If you or your child experiences any symptoms, you will be treated immediately and all medication necessary to treat you will be immediately available.

I have read the above information and understand the purpose of the test and the associated risks. With this knowledge I agree to have this test performed on my child or me.

Print Name
Patient or Guardian

Signature

Date

Print Name
Witness

Signature

Date

Appendix VIII Sample Methacholine Challenge Pre-Test Questionnaire

(Modified from Appendix B of [2017 ERS technical standard on bronchial challenge testing: general considerations and performance of methacholine challenge tests](#))

First Name: _____ Last Name: _____

Date of Birth (Year/Month/Day): _____/_____/_____

Medical Record or ID Number: _____

- List all medications you have taken in the last 3 days for asthma, hay fever, heart disease, blood pressure, allergies, or stomach problems, and the number of hours or days since your last dose for each medication.

Name of Medication	Date and time of last treatment

	Yes	No	
2.			Has a physician told you have asthma?
3.			Have you ever been hospitalized for asthma?
4.			Did you have recurrent episodes of cough and wheezing or lung infection as a child?
5.			Have you experienced asthma symptoms such as wheezing or shortness of breath within the last two weeks?
6.			If you are a smoker, when did you last smoke? Hours/Minutes
7.			Have you had a respiratory infection in the last 6 weeks?
8.			Have you had a heart attack or stroke within the last 3 months?
9.			Do you have high blood pressure? Systolic/Diastolic:
10.			Do you have an aortic aneurysm? Size: cm
11.			Have you had recent eye surgery? How long ago? Days/Months
12.			Female Only: Are you pregnant or nursing?

