

CARDIAC CARE NETWORK



Standards for the Provision  
of Electrocardiography (ECG)-Based  
Diagnostic Testing  
in Ontario  
2017



**CARDIAC CARE NETWORK**



4100 Yonge St., Suite 502

Toronto, ON M2P 2B5

tel: 416-512-7472

fax 416-512-6425

[www.ccn.on.ca](http://www.ccn.on.ca)

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# Standards for Provision of Electrocardiography-Based Diagnostic Testing in Ontario (2016)

## Foreword

CCN has a solid history of advising the Ministry of Health and Long-Term Care (MOHLTC), Local Health Integration Networks (LHINs), hospitals and care providers to improve the quality, efficiency, accessibility and equity of cardiac services for patients across Ontario. Currently, CCN's mandate has expanded to include the management of vascular and more recently stroke services for patients and providers in Ontario.

CCN has played an integral role in enhancing health system improvements in Ontario through the use of a more proactive, comprehensive and transparent approach to the planning, funding, performance management, and ongoing quality improvement of cardiac and vascular systems of care in Ontario. In partnership with the Ministry, and other stakeholders, CCN's growing mandate will include emphasis on improved system design, capacity planning, funding policy, and performance management.

Through scientific evidence, expert panels and working groups, CCN uses evidence and consensus driven methods to identify best practice and strategies to effectively deliver cardiovascular services, across the continuum of care.

CCN is committed to improving the quality of cardiovascular care in Ontario, including the development of guidelines and standards related to selected cardiac diagnostic tests.

This document has been developed by CCN's Heart Rhythm Working Group - Electrocardiography Subcommittee. The purpose of this document is to:

1. Develop standards related to selected electrocardiography (ECG)-based diagnostic tests.
2. Describe a process to enable providers to adopt these standards.

## Introduction

ECG-based diagnostics have evolved substantially since Willem Einthoven first recorded an ECG with a string galvanometer in 1902. The years since have seen the development of the 12-lead ECG, continuous extended ECG monitoring, exercise stress testing, and even the development of implantable ECG monitors capable of automated arrhythmia detection. As these tests and their indications have expanded, however, so too has their financial impact.

The Panel responsible for drafting the recommendations contained in this document was convened under the auspices of the Cardiac Care Network of Ontario. The aim of this document is to ensure that ECG-based diagnostic tests in Ontario are performed with the highest level of quality for clinically appropriate indications. These recommendations may also serve to develop robust standards by which the provision of ECG services can be evaluated and reviewed to ensure ongoing quality and appropriate utilization. Through this process of information dissemination and self-review, we hope that practitioners will continue to provide the best possible service to enhance the welfare of our patients.

Atul Verma MD, FRCPC  
Cardiac Electrophysiologist  
Director, Heart Rhythm Program  
Southlake Regional Health Centre  
Newmarket, Ontario  
University of Toronto

# CCN Ontario Heart Rhythm Working Group Electrocardiography Subcommittee 2016

## Electrocardiography-Based Diagnostics Standards Subcommittee - Primary Panel

Atul Verma MD – Chair, Southlake Regional Health Centre, Newmarket, Ontario  
Eugene Crystal MD – Sunnybrook Health Sciences Centre, Toronto, Ontario  
Paul Dorian MD – St. Michael's Hospital, Toronto, Ontario  
Martin Green MD – Ottawa Heart Institute, Ottawa, Ontario  
Milan Gupta MD – McMaster University, Hamilton, Ontario  
Andrew Ha MD – Toronto General Hospital, Toronto, Ontario  
Jeff Healey MD – Hamilton Health Sciences Centre, Hamilton, Ontario  
William G Hughes MD – Peterborough, Ontario  
Amir Janmohamed MD – Rouge Valley Health Sciences Centre, Scarborough, Ontario  
Paul Oh MD – Toronto Rehabilitation Institute, Toronto, Ontario  
Damian Redfearn MD – Kingston General Hospital, Kingston, Ontario  
Robert Wald MD – Mount Sinai Hospital, Toronto, Ontario  
Raymond Yee MD – London Health Sciences Centre, London, Ontario

## Secondary Review Panel

David Newman MD – Sunnybrook Health Sciences Centre, Toronto, Ontario  
Louise Harris MD – University Health Network, Toronto, Ontario  
Sammy Chan MD – St. Pauls' Hospital, Providence Health Care, Vancouver, British Columbia  
John Fulop MD – Ottawa Hospital, Ottawa, Ontario  
Blair O'Neill MD – Alberta Health Services, Edmonton, Alberta  
Steve Radke MD – Renfrew Victoria Hospital, Renfrew, Ontario  
Anthony Graham MD – St. Michael's Hospital, Toronto, Ontario

## CCN Staff

Elizabeth Berry, RN, BHA. Clinical Lead Heart Rhythm, Cardiac Surgery, and TAVI  
Vevien Braga, RN, MHS. Senior Clinical Lead  
Anne Forsey, RN, MHS. Director Clinical Services



# Standards for Provision of Electrocardiographic-Based Diagnostic Testing in Ontario

Electrocardiographic (ECG)-based diagnostic testing represents a large spectrum of diagnostic procedures within cardiology. The four key categories include the following:

1. 12-lead Electrocardiogram (ECG);
2. Ambulatory ECG Monitoring (AEM)<sup>1</sup>;
3. Insertable Cardiac Monitor Recorders (ICM); and
4. Exercise ECG Stress Testing (EST).

The four categories of ECG-based diagnostic testing represent approximately 4.7 million tests ordered in 2014 in the province of Ontario. (Medical Services, IntelliHEALTH Ontario, Ministry of Health and Long-Term Care, 2014) To date, little exists in the way of a standards framework to ensure quality ordering, administration, and interpretation of these tests in the province. Thus, the purpose of this document is to provide a comprehensive definition of requirements for provision of high quality ECG-based diagnostic testing in Ontario.

This document is structured in a format that represents the patient journey through ECG-based diagnostic testing. This includes the initial referral for testing, confirmation notification sent to the referring Health Care Provider from the testing facility, and accurate storage of test results for future reference. Definitions and detailed descriptions of ECG-based tests are provided in **Appendix A**.

The specific requirements of each type of laboratory may differ according to the services offered and are covered in later sections of this document.

The development of this document included a detailed literature review of previously published standards, guidelines and recommendations (from national and international committees) to serve as a foundation for the Ontario standards. The document also proposes a framework for self-assessment against these standards for laboratories that provide ECG-based services in Ontario.

For the purposes of this document, the term “laboratory” will be defined as a facility that regularly provides ECG-based diagnostic testing. It is recognized that facilities vary greatly in size, scope of service provided (i.e., one or more of ECG, AEM, and EST), site (i.e., private office, clinic, hospital) and setting of

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<sup>1</sup> Within AEM, there are several modalities of testing including ambulatory Holter monitoring of various durations and external (loop) event recorders (EER).

**Note:** In 2016 OHTAC reviewed both external cardiac loop recorders and long term continuous ambulatory ECG monitors to examine which test would provide more efficient use of resources. OHTAC has recommended that patient-activated external cardiac loop recorders (no continuous or automated recording) will no longer be a funded diagnostic test.

examinations provided (i.e., inpatient, outpatient, emergent); however, there are components common to all sites related to the following features:

- Process for accepting and screening referrals for ECG-based diagnostic testing;
- Provision of space, equipment, and procedures to provide such testing;
- Retention of results of such testing;
- Engagement of appropriately trained healthcare professionals to carry out the provision of such testing; and
- Engagement of appropriately trained physicians to interpret, report, and supervise the examinations, and to oversee quality assurance processes.

There are six key components in the process of conducting clinical electrocardiography:

1. Receipt of referral and review of indication for test;
2. Recording of the test and linkage of patient demographics to the tracing;
3. Data storage and transfer;
4. Interpretation of the test/tracings;
5. Communication of results to the referring physician; and
6. Quality assurance to ensure accuracy of the patient information and test results.

A conceptual framework will be provided in the following six sections describing the characteristics of optimal service provision. In addition, **standards** will be described or defined as **demonstrable performance characteristics that provide evidence of quality service provision**. In their entirety, standards provide a means of identifying appropriate service and ensuring all patients receive timely and effective assessment.

**Section 1:** Referrals and Indications for ECG-Based Diagnostic Tests

**Section 2:** Performing ECG-Based Diagnostic Tests

**Section 3:** Interpretation, Reporting and Communication of Results

**Section 4:** Facilities, Equipment, and Standard Operating Procedures

**Section 5:** Program Administration and Human Resources

**Section 6:** Continuing Quality Assurance

**Section 7:** Framework to Assess Facilities against the Standards

## Appendices

**Appendix A:** Abbreviations and Definitions

**Appendix B:** Indications for ECG-Based Diagnostic Testing

**Appendix C:** Selection of ECG-Based Modality and Sample Testing Protocols

**Appendix D:** Standard Information Required for ECG-Based Reports

**Appendix E:** Facility and Equipment Considerations

**Note:** Within this document the term “shall” is used to express a requirement that facilities providing ECG-based diagnostic tests are obliged to satisfy in order to comply with the standard.

## Section 1: Referrals and Indications

**As a guiding and overriding principle, it is recommended that the use of ECG-based testing be performed if, and only if, the results have the potential to influence clinical decisions and patient management.**

**For patients with suspected ischemic heart disease, it is recommended that non-invasive testing be completed within 2 weeks of initial assessment (Mancini et al., 2014).**

Electrocardiography is a non-invasive diagnostic technique that provides quantitative information relevant to cardiac rhythms. It therefore has a key role in the assessment of patients presenting with numerous clinical problems.

In developing the list outlined in **Appendix B**, the panel was cognizant of the primary role of the treating physician in determining the utility of diagnostic testing or therapeutic intervention and the wish to neither deny patients the potential benefit of this technique nor suggest that all patients presenting with particular issues would necessarily benefit from electrocardiographic assessment or treatment.

**Appendix B** lists indications in which electrocardiographic-based testing or implantation of cardiac monitor recorders is known to have an impact.

### Standard 1.1: Referrals

#### Standard 1.1.1: Referring Healthcare Provider (HCP)

Referrals for ECG based diagnostic testing shall be made by a primary care provider or specialist whose role includes caring for the patient.

#### Standard 1.1.2: Components of Referrals

All orders or referral requisitions for ECG-based diagnostic testing procedures shall include at a minimum:

- The diagnostic test to be performed;
- A standard indication (refer to **Appendix B**);
- The name of the referring physician;
- Patient demographics;
- Relevant cardiac comorbidities (Mancini et al. 2014);

- The urgency of the test;
- The contact number for the ordering physician in case of an urgent/critical result; and
- The contact number for the patient in case of an urgent/critical result.

### **Standard 1.1.3: Referral Triage**

The ECG Based Diagnostic testing facility shall have standardized process for the triage of referrals to ensure urgent requests are performed in a timely manner.

### **Standard 1.1.4: Communication with Patients**

The patients referred for an ECG-Based diagnostic test shall be notified of the testing date by the facility within 2 weeks of referral. The patient shall also be provided the following information:

- Specific pre-test instructions; and
- Obtaining test results and/or copy of ECG.

**Note:** All communication shall maintain patient confidentiality as outlined by the 2004 Personal Health Information Protection Act.<sup>2</sup>

## **Standard 1.2: Documentation of Indication**

Electrocardiographic laboratories shall have mechanisms that ensure that an indication is documented as a component of every referral. In cases where the ordering specialist physician is the same as the reading physician, an indication shall be included as part of the consultation letter.

## **Standard 1.3: Referral for AEM – Additional Requirement**

The referral for AEM shall also include sufficient information to enable the laboratory to determine the appropriateness of the test and technique (e.g., Holter, External Event Recorder (EER))

## **Standard 1.4: Mechanism for Tracking Indications**

Electrocardiographic laboratories shall have mechanisms to ensure indications are tracked for all completed studies and meet standards as outlined in **Appendix B** for at least 95% of studies and implantations completed.

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<sup>2</sup>Personal Health Information Protection Act (PHIPA). (2004). S.O. 2004, c. 3, Sched. A. Retrieved February 9, 2017 at <https://www.ontario.ca/laws/statute/04p03>

## **Standard 1.5: Referrals without Indications**

For referrals received without a standard indication (as per **Appendix B**), laboratories shall have mechanisms whereby referring physicians are contacted for clarification before the study is carried out.

## **Section 2: Performing ECG-Based Diagnostic Tests**

### **Standard 2.1: Protocols for All Tests**

ECG-based testing facilities shall have established protocols that describe the components of each test provided. Protocols for the acquisition and recording of the ECG-based tests for each modality shall be in place and available to all, and revisited on a regular basis. These protocols shall be reviewed and accepted by all qualified operators and physicians involved in acquisition, recording, interpretation, and reporting of such tests.

### **Standard 2.2: Protocol for Electrode Placement**

ECG-based testing facilities shall have established protocols that describe the electrode sites for a comprehensive 12-lead ECG including accommodation for patients with special needs.

The positioning of the standard 12 leads will be in accordance with published guidelines as variation can invalidate the use of such recording for many diagnostic purposes (Mason et al., 2007). The operator shall adapt the ECG recording techniques for a patient with special needs (i.e., amputees) and will clearly label them on the printed ECG.

### **Standard 2.3: Patient Education**

For AEM, Holter, and EERs tests, patients shall be provided instruction on how to activate the device event marker and document symptoms in the diary log. The patient shall be able to demonstrate back to the operator proper equipment use.

For ICM tests, patients shall be provided instruction on the post insertion care of an Insertable Cardiac Monitor Recorders (ICM).

### **Standard 2.4: Additional Requirements – ICM, EST**

#### **ICM**

ICM shall be used in collaboration with specialists that are associated with an arrhythmia device program.

### **EST and Metabolic Exercise Test (MET)<sup>3</sup>**

All patients undergoing EST and MET shall have a 12-Lead ECG prior to performing the test.

- For patients suspected of having stable ischemic heart disease, noninvasive diagnostic testing should be performed within 2 weeks of initial assessment (Mancini et al., 2014). These tests inform the diagnosis and prognosis, guide the exercise prescription and suggest the response to therapy.
- Continuous oscilloscopic monitoring of a minimum of three leads will identify arrhythmia patterns; however, the ability to produce a 12-lead printed copy will enhance interpretation and is highly recommended.
- EST testing can be accomplished using treadmills, cycle ergometers, or cycle arm ergometers. Detailed descriptions are available in **Appendix A**.
- The use of ventilator-expired gas analysis using computerized metabolic systems greatly improves both accuracy and reproducibility for assessing cardiopulmonary function compared with indirect estimation of oxygen uptake from work rate.

A variety of EST protocols exist in order to customize the level of exercise required to determine the existence of a clinical condition. For most tests, this will involve the use of the Bruce protocol. For patients in whom it is anticipated that they will have lower exercise output, or in patients who cannot exercise a full protocol due to physical limitations, a modified protocol may be considered. These protocols, such as the modified Bruce or Naughton protocols, involve slower initial stages with less aggressive progression between stages. Details of the Bruce, modified Bruce, and Naughton protocols are provided in **Appendix C**.

## **Section 3: Interpretation, Reporting and Communication of Results**

### **Standard 3.1: ECG Interpretation**

All ECG interpretations shall be confirmed by a physician who has met the competency requirements outlined in Appendix F.

The computer-generated interpretation of a 12-lead electrocardiogram that has not been confirmed by a trained physician is inadequate for diagnosis. All ECG laboratories shall have protocols to ensure documentation of the physician's confirmation of the interpretation and shall include "Confirmed by Dr. [insert name] on [insert date] at [insert time]".

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<sup>3</sup> This standard deals exclusively with exercise ECG stress testing and does not cover pharmacologic stress testing or ECG stress testing with additional imaging such as nuclear or echocardiography.

There are scenarios where nurses or paramedics are delegated the responsibility for ECG interpretation for urgent management. In these cases, the final interpretation and reporting of the ECG shall be performed by a trained physician. The delegated professionals shall have access (remote or otherwise) to a physician for assistance with interpretation of the ECG if required.

**Note:** *It is not the responsibility of the technician to generate final reports, nor should they be compelled to report preliminary findings to the patient.*

### **Standard 3.2: ECG-Based Diagnostic Test Reports**

All ECG-based diagnostic test reports shall include the information outlined in **Appendix B and D**.

### **Standard 3.3: Previous ECG**

When a previous ECG(s) is readily available, the reading physician shall compare the results of the electrocardiogram to the most recent available ECG.

### **Standard 3.4: Notification of Results**

Laboratories shall have a notification protocol whereby critical and urgent findings are communicated immediately by the interpreting physician to the referring physician and/or patient. A list of critical findings for each modality can be found in **Appendix D**.

### **Standard 3.5: Timeframes for Reporting**

ECG-based diagnostic testing reports shall be provided within the following timeframes:<sup>4</sup>

- The **ECG** report shall be available within two (2) business days for inpatient studies and within seven (7) business days for outpatient studies;
- The **AEM** report shall be available within 10 days from the end of the testing period;
- Abnormal, but not critical, outpatient AEM results shall be reported within a maximum of seven (7) days;
- The **ICM** report shall be available within 10 days from the transmission time; and
- The **EST** (including MET, if performed) report shall be available within five (5) days.

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<sup>4</sup> With the exception of critical situations outlined in Appendix D.

### **Standard 3.6: Amended Reports**

Amended reports shall be identified as such and shall include the date and time of the change, as well as the specific changes from the original report. Amended interpretations shall be communicated to the referring physician in a timely manner as outlined in **Standard 3.5**.

### **Standard 3.7: Final Reports**

Final reports shall be in a consistent format and completed only after full review of all acquired data, necessary re-testing, and include the information outlined in **Appendix D**.

**Note:** *Incorporating the findings into a consultation letter is not sufficient with the exception of a 12-lead ECG.*

### **Standard 3.8: Modes of Communication**

The final report results shall be communicated via one of the following:

- Paper copy through surface mail;
- Electronic transmission (e.g., private dedicated fax to physician, secure and encrypted electronic transmission);<sup>5</sup>
- Secure website posting accessible to physicians upon notification of report availability; or
- Telephone in the event of potentially life-threatening arrhythmias (see list of **Critical Findings in Appendix D**).

### **Standard 3.9: Storage of Information**

Electrocardiographic data (measurements and final reports) obtained for diagnostic purposes shall be recorded, stored and archived in a format that ensures ready retrieval, complete review, clear communication and patient confidentiality.

### **Standard 3.10: Retention of Record**

A permanent record of the diagnostic test shall be retained in accordance with provincial guidelines for medical records (also refer to **Standard 4.3.1**).

Additional details regarding reporting for specific ECG-based examinations are outlined in **Appendix D**.

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<sup>5</sup> CMA policies for fax transmission are outlined in CMAJ October 15, 1995 vol. 153. No 8.



## Section 4: Facilities, Equipment and Standard Operating Procedures

In Ontario, ECG-based diagnostic testing can be performed in a number of settings with varying degrees of patient acuity. Typical settings include hospitals, clinics (hospital and/or community), and physician offices.

The examination room requirements are based on the specific test to be performed. It is important that rooms facilitate patient privacy and comfort, and are ergonomically designed for the technologists performing the examination.

### 4.1 The Electrocardiography Facility

#### Standard 4.1.1: Examination Rooms

The examination rooms where ECG-based tests are performed shall provide, at a minimum, the following:

- A large enough space to accommodate all the equipment necessary, while maintaining walking areas and ensuring adequate access to the patient in emergency situations;
- A testing room that is well lit, and clean;
- A private area for patient preparation, testing and recovery (where appropriate) with a curtain or partition for privacy during patient preparation;
- Hand hygiene products and/or a sink with antiseptic soap must be readily available for hand washing in accordance with the infection control policy of the facility; and
- An examining bed which facilitates patient comfort.

#### Standard 4.1.2: Facilities Performing Ambulatory ECG Monitoring (AEM)

In addition to requirements outlined in **Standard 4.1.1**, facilities performing AEM shall provide both technical and professional aspects of AEM service (see **Appendix E**).

#### Standard 4.1.3: Facilities Performing Insertable Cardiac Monitor Recorder (ICM)

The surgical implantation of cardiac monitor recorders shall be performed in a facility that conforms to the standards set by the Canadian Association for Accreditation of Ambulatory Surgery Facilities and shall include:

- An operating room suite or equivalent providing a sterile environment (e.g., procedure room, catheterization laboratory, electrophysiology laboratory);

- A post-anesthetic care unit or equivalent space for patient recovery after implant;
- Facilities for surgical instrument sterilization; and
- An arrhythmia device clinic for monitoring and follow-up of the patient.

Additional guidelines on the space, equipment, and drug storage for safe and aseptic treatment of the patient are available through the Canadian Association for Accreditation of Ambulatory Surgery Facilities (<http://caaasf.org/>).

#### **Standard 4.1.4: Facilities Performing Exercise Stress Testing (EST)**

In addition to requirements outlined in **Standard 4.1.1**, larger rooms shall be provided to perform EST, in order to accommodate extra equipment, personnel and potential resuscitation procedures and shall also provide the following:

- The examination room must be large enough to accommodate all advanced emergency equipment, a defibrillator, and medications for urgent resuscitation while maintaining adequate walking areas and access to the patient in emergency situations.
- The examination room must be well ventilated, with temperature (20-22 °C) and humidity (<60%) control.
- A large-print scale of perceived exertion mounted on the wall in clear view of the patient, to assess the level of effort.<sup>6</sup>
- Handheld scales for use during cardiopulmonary testing when the mouthpiece or mask may prevent speech. These scales shall be clearly explained to the patient before testing is initiated (Myers et al., 2009).

#### **Standard 4.1.5: Additional Requirement - EST**

Facilities performing EST shall have procedures regarding the observation and recovery of patients by appropriately trained and qualified personnel, and shall have the following:

- An examination bed appropriate to patient recovery and observation; and
- Staff that is certified in Basic Cardiac Life Support (BCLS).

## **4.2 Equipment Required to Perform ECG–Based tests**

Fully-equipped, highly-functioning and well-maintained equipment is essential for optimal examinations. Regular equipment maintenance by appropriately-trained individuals is essential. The majority of

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<sup>6</sup> Either the original (category) Borg scale, which rates intensity on a scale of 6 to 20, or the revised (category-ratio) scale of 1 to 10 is appropriate as a subjective tool for exercise testing. Simpler 1 to 4 scales are preferable to quantify symptoms of angina or dyspnea.

modern ECG systems will also include digital or secure web-based storage of ECGs for easy retrieval and reproduction for comparison between studies.

Most modern ECG machines also provide automated interpretations to aid physician reporting. Each ECG laboratory shall calibrate and ensure that its computer system follows the American College of Cardiology/American Heart Association (ACC/AHA) definitions in providing automated ECG diagnoses (Kligfield et al., 2007; Mason et al., 2007). It is the responsibility of the interpreting physician to ensure that the automated ECG diagnoses are accurate and congruent with established standards. Physicians should not solely rely on using automated diagnoses when interpreting ECGs.

#### **Standard 4.2.1: Equipment Requirement**

Equipment for all ECG-based tests shall conform to standards published by the American Heart Association (AHA) (Kadish et al., 2001).

For full details, the reader is directed to the AHA published standards referred to in this section with the principles listed below:

1. Appropriate filter settings – high pass (0.05 Hz) and low pass filters (at least 150 Hz) are standard and a notch filter (alternating current filtering) may be used to help to attenuate noise artifact from the recording (Bailey et al., 1990);
2. Ability to simultaneously record the standard 12 leads of the ECG and also have the capability to change to frequently used lead placement variations (right sided leads, high precordial leads);
3. Global measurement of intervals and durations from simultaneously recorded ECG leads P and QRS durations; PR, QRS, and QT intervals; corrected QT interval; and QRS axis. These recordings represent a minimum of automated measurements that are to be included directly on the ECG for interpretation; and
4. Data compression, storage, and retrieval – compression algorithms used for digital storage that allow for ECGs to be retrieved within fidelity of 10  $\mu$ V.

#### **Standard 4.2.2: Key Components of Equipment**

A laboratory that performs ECG-based testing for the clinical management of patients shall encompass these key components:

1. A digitally-based ECG acquisition system capable of displaying, printing, storing and transferring of 12-lead ECGs;
2. Link patient demographics to the ECG tracing; and
3. Clinical and technical staff to support the accurate interpretation of the ECG.

#### **Standard 4.2.3: Equipment Maintenance**

Machines and equipment shall be regularly maintained according to manufacturer specifications, and undergo at least annual calibration and quality control testing including:

- Recording of the method and frequency of maintenance of all ECG-based diagnostic testing equipment;
- Establishment of and adherence to a policy regarding routine safety inspections and testing of all electrical equipment; and
- Establishment of and adherence to an instrument cleaning schedule that includes routine cleaning of equipment parts, according to manufacturer specifications.

Additional details for specific ECG-based examination equipment are outlined in **Appendices D and E**.

## **4.3 Standard Operating Procedures for Facilities Providing ECG-Based Tests**

### **Standard 4.3.1: Storage of Records**

ECG-based records shall be stored for a minimum of 10 years in accordance with the College of Physicians and Surgeons Policy Statement (May 2012).

### **Standard 4.3.2: Laboratory Policies and Protocols**

Laboratories shall have policies and protocols outlining the following:

- Steps required for the application of equipment (e.g. skin preparation and electrode positioning), scanning and analysis, physician interpretation, report format, and report distribution;
- Notification protocol for critical and urgent findings;<sup>7</sup>
- Roles, qualifications and responsibilities of all staff in the laboratory; and
- Requirements of continuing education for all staff.

### **Standard 4.3.3: Infection Prevention and Control (IPAC) Policies and Protocols**

ECG-based laboratories shall have IPAC policies and protocols in place.

All health care providers shall follow routine IPAC practices for all patients during care in ECG laboratory settings. Protocols shall contain the following elements of routine IPAC practices:

- Hand Hygiene;

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<sup>7</sup>This policy should in no way be interpreted as a substitute for urgent access to physician backup and interpretation.

- Risk Assessment;
- Personal Protective Equipment (PPE);
- Control of the Environment;
- Cleaning the Environment;
- Safe Administration of Injectable Medications (where applicable);
- Cleaning of Medical Equipment; and a
- Healthy Workplace Policy.

#### **Standard 4.3.4: Informed Consent**

All procedures shall be explained to the patient and/or the substitute decision maker of those unable to give informed consent. Consent shall be obtained and documented in a manner consistent with the rules and regulations outlined by the hospital or facility.

#### **Standard 4.3.5: Additional Requirement for Metabolic Exercise Test (MET)**

The system used for metabolic exercise testing shall be calibrated immediately before each exercise test including:

- Calibration of airflow ventilatory volume and both oxygen (O<sub>2</sub>) and carbon dioxide (CO<sub>2</sub>) analyzers.

## **Section 5: Program Administration & Human Resources**

It is possible for one individual to assume multiple roles in an ECG laboratory. In many cases, however, multiple individuals will comprise the personnel of the ECG laboratory. The minimal human resource infrastructure of an ECG-based laboratory shall include a medical director, business manager, database manager, person who acquire ECGs and physicians who supervise and interpret ECGs.

### **5.1 The Medical Director**

#### **Standard 5.1.1: Medical Director**

The laboratory will have a designated medical director, who shall be a licensed physician, preferably a cardiologist, with experience in all important aspects of clinical electrocardiography. The medical director may also be an internal medicine specialist with experience in all aspects of electrocardiography.

### Standard 5.1.2: Roles and Responsibilities

The medical director shall carry out and/or have oversight for the following:

- All clinical services provided and determination of the quality and appropriateness of care;
- Assuring compliance and competence of the medical and technical staff to these standards and the supervision of their work in all areas where electrocardiographic examinations occur;
- Active participation in the interpretation of tests performed in the laboratory;
- Ensuring the quality and timeliness of reports;
- Being aware of newly approved technologies and the ability to make adjustments to requisitions and technologies as they become clinically relevant;
- A quality assurance process including random sampling of reports, both internal and external periodic reviews, and documentation of QA audits to ensure accuracy and completeness;
- Annually approving the equipment's condition based on actual recordings; and
- For laboratories with multiple sites, the medical director is responsible for ensuring all standards are consistently followed at all sites.

The medical director of an ECG laboratory is responsible for all aspects of clinical electrocardiography at that facility. The medical director can delegate these tasks to specific individuals who are part of the ECG-based laboratory; however, the medical director is ultimately responsible for the overall quality and accuracy of ECG-based acquisition, interpretation, and reporting of the laboratory.

## 5.2 Medical Staff

### Standard 5.2.1: Medical Staff

The medical staff interpreting 12-lead ECGs shall be licensed physicians. In particular, expertise in the following areas is recommended for the interpretation of ECGs:

- Knowledge of the upper and lower ranges of normal ECG measurements;
- Recognition of ECG artifacts generated from technical errors in ECG acquisition;
- Awareness of new ECG diagnostic criteria in the published literature;
- Awareness of new technology in clinical electrocardiography; and
- Knowledge of the wording of automated statements of the ECG interpretation software.

**Recommendation:** *An efficient testing program should be developed to certify physicians in ECG interpretation to ensure minimum competency for physicians in the province of Ontario.*

### Standard 5.2.2: Specific Training

Medical staff providing specialized ECG testing shall have specific training in cardiac electrophysiology preferably with advanced training in genetic syndromes.

- There are some instances where specialized ECG testing, such as signal-averaged ECG or drug-provocation testing with 12-lead ECG monitoring, will be performed for rare, genetic arrhythmia syndromes.

**Recommendation:** *Specialized drug provocation testing with 12-lead ECG monitoring that are performed for rare, genetic arrhythmia syndromes shall only be undertaken by a cardiologist with specific training in cardiac electrophysiology.*

### **Standard 5.2.3: Additional Training - AEM**

Medical staff providing AEM testing shall have the minimum qualifications as outlined in **Standard 5.2.1** with the following additional qualifications:

- The physician shall also have documented performance in AEM, with the interpretation of 100 in each modality under expert supervision in an established laboratory prior to providing interpretation and maintenance of competence with a minimum of 25 scans in each modality per year.

### **Standard 5.2.4: Additional Training – ICM**

Medical staff interpreting ICMs shall be electrophysiologists or physicians with cardiology certification and advanced arrhythmia training with specific rotations or training in device [minimum pacemaker] management.

Medical Staff inserting ICMs shall be cardiologists or cardiovascular surgeons with experience in implantation of pacemakers and/or implantable defibrillators.

- The inserting/implanting and interpreting physicians of ICMs do not necessarily have to be the same individual.

### **Standard 5.2.6: Additional Training - EST**

Medical staff supervising and/or interpreting EST shall have the minimum education, training, experience, cognitive and procedural skills necessary for competent performance and interpretation of EST as outlined in the ACC/AHA/American College of Physicians “Clinical Competence Statement on Stress Testing, 2000”.

Healthcare professionals from several disciplines (e.g., exercise physiologists, nurses, nurse practitioners, physician assistants, and medical technologists) may possess the training and experience required to perform competently as supervisors of EST. Appropriate training and information about the

cognitive and performance skills necessary to competently supervise exercise tests are available in published guidelines (Rogers et al., 2000).

#### **Standard 5.2.7: Additional Responsibility - EST**

Medical staff supervising EST shall remain onsite during testing and are responsible for:

- Rapidly interpreting the data during a test if required;
- Suggesting further evaluation or additional techniques for testing, if needed; and
- Delivering appropriate emergency care when necessary.

The supervising physician may or may not be the same physician providing the final interpretation of the EST. However, in such cases, both the supervising and interpreting physicians shall meet the basic competency requirements listed above.

#### **Standard 5.2.8: Additional Training - MET**

Medical staff supervising and/or interpreting MET requires additional knowledge and training.

- More advanced training is required for performance of additional cardiopulmonary testing in addition to the standard ECG EST. Knowledge of the equipment, its operation, the variables acquired and the interpretation of these cardiopulmonary variables is required for this type of specialized EST for both the technologist acquiring the test and the supervising/interpreting physician; and
- A minimum of 20 such examinations shall be carried out at the laboratory per year for both the technologists and physicians to maintain their competency.

Additional details for specific ECG-based examination knowledge are outlined in **Appendix F**.

## **5.3 Managers of ECG-Based Testing Facilities**

#### **Standard 5.3.1: Business Manager**

The ECG-based diagnostic testing laboratory shall have a designated business manager, who is responsible for the daily operations including:

- Staff employment;
- General supervision and technical training of all staff;
- Budget management;
- The delegation, where appropriate, for specific responsibilities of the technical or support staff;
- Operation and maintenance of laboratory equipment; and
- Delivery of quality patient care.



### **Standard 5.3.2: Data Manager**

The ECG-based diagnostic testing laboratory shall have a designated data manager, who is responsible for:

- Quality assurance in data acquisition;
- Report storage and transfer;
- Assisting in the communication of reports to referring physicians;
- Maintenance of relevant electronic/data systems; and
- Maintaining service contract agreements with biomedical engineering or technical support team of the relevant equipment in order to:
  - Ensure that technical errors and any malfunctions are promptly and effectively addressed; and
  - Facilitate the integration of up-to-date technology in the ECG laboratory.

## **5.4 Personnel Providing ECG-Based Testing**

### **Standard 5.4.1: Laboratory Staff - ECG**

**The laboratory shall have designated staff who have received formal training in the acquisition of ECGs.**

It is recognized that there are health care providers who graduated before there was a formal certification program and non-healthcare professionals (e.g., office administrative assistants) who acquire ECGs. In this case it may be appropriate for these individuals to continue acquiring ECGs. These individuals are required to pursue educational activities to maintain and refine their skills in ECG acquisition.

In many healthcare settings, 12-lead ECGs are acquired by Nurses (RN and RPNs). Nurses should receive training in ECG acquisition either in their core education program or from individuals such as nurse educators.

### **Standard 5.4.2: Laboratory Staff - AEM**

The AEM laboratory shall have designated Nurses or Cardiovascular Technologists<sup>8</sup> who have received formal, specific training in performing AEM.

Nurses and Technologists responsible for the acquisition of AEM must be trained in:

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<sup>8</sup> Cardiovascular technologists graduate from a two year training program, after which certification is achieved by passing a licensing exam from the Canadian Society of Cardiology Technologists (CSCT).

- Skin preparation, and electrode positioning/fixation;
- Educating the patient on how to use the device and symptom diary, how to change and apply electrodes, and how to transmit events;
- Scanning the returned data from the patient; and
- Provide tracings of adequate detail, duration, and quality for the physician to interpret.

#### **Standard 5.4.3: Clinic Staff – Cardiac Devices**

Cardiac device clinic staff shall be trained in remote monitoring and have a system by which transmissions are collected, triaged, and reviewed with the attending physician.

Most device clinic staff are RNs with specialized training, although technologists with advanced training may also participate. Staff must receive education on remote monitoring and be trained in the management of implanted cardiac devices such as pacemakers (at a minimum) in order to follow ICM.

Device clinic staff shall also provide:

- Patient education on ICM equipment;
- Receipt and processing of transmissions;
- Wound assessment; and
- ICM report communication to ordering physician.

**Note:** *Industry representatives should not be involved in the delivery of direct patient care, rather serve in an education and advisory role (Yee, et al 2013).*

#### **Standard 5.4.4: Implant Staff**

Staff working in ICM implant rooms shall be health professionals who possess the necessary training and qualifications in operating room (OR) practices as well as device interrogation.

- Staff in ICM facilities shall consist of RNs or cardiovascular technologists with specialized training in OR techniques and device interrogation/implantation.

#### **Standard 5.4.5: Laboratory Staff - EST**

Staff working in examination rooms where EST is performed shall have specific training in performing exercise stress testing. Staff responsible for the acquisition of the stress ECG must be trained in specific skills which include:

- Skin preparation and electrode positioning/fixation;
- Screening of the ECG to ensure it is appropriate for stress testing (i.e., absence of left bundle branch block);

- Acquisition of accurate manual blood pressure by auscultation during the administration of the test;
- Distinctly abnormal automated blood pressure recordings during exercise must be corroborated by manual measurement (recordings must be made with the appropriate size cuff);
- Recognition of potentially emergent or life-threatening ECG changes or arrhythmias that may require cessation of the test or initiation of emergency protocols (Thompson. et al 2010) ; and
- BCLS certified and trained in use of defibrillator.

In addition, staff working in EST shall be prepared for emergencies that may arise during the administration of an EST including:

- A written emergency plan that is rehearsed quarterly; and
- Clear plan for rapid transfer of unstable patients by a specified route to hospital emergency facilities.

## **Section 6: Continuing Quality Assurance in the ECG-Based Testing Laboratory**

The ECG-based testing laboratory is expected to develop, describe, and make available its own internal quality assurance (QA) program or to partner with a reference laboratory with an established QA program. The QA program shall include methodology, implementation, documentation, and review that address the following standards:

### **Standard 6.1: Review of Study Acquisition**

Protocols and processes shall be in place to regularly review the quality and completeness of the ECG. This is a function that might be satisfied by regular review of a set number of random studies over a set time interval, using a pre-defined point-score system, and pre-set standards of accuracy under the auspices of the Medical Director or his/her designate.

### **Standard 6.2: Review of Study Interpretation**

This is accomplished by reconciling study interpretation with protocols and processes in order to review the accuracy, completeness, and timeliness of the reports of each interpreting physician. This function may be satisfied by a regular review of a set number of random interpretive reports over a set time interval using a pre-defined point-score system and pre-set standards of accuracy by the Medical Director or his/her designate(s). To ensure quality interpretation and to assist with internal audit processes, two percent of all scans interpreted by a physician shall be cross-read by the Medical Director or another interpreting physician.

### **Standard 6.3: Staff Meetings**

Scheduled staff meetings shall be held to review patient care processes, discuss the results of the quality assurance process and introduce system-wide improvement measures. Minutes of the staff meetings shall be documented and maintained for staff to review.

### **Standard 6.4: External Review**

An external review process shall be in place that allows for constructive feedback and review of either confirmatory or discordant findings by other laboratories.

### **Standard 6.5: Case Review**

Organization of and/or attendance at rounds and/or conferences focused on interesting case reports or series cases, or specific disease entities with an instructional content relevant to the ECG program.

**Note:** *The Personal Health Information Protection Act is applicable whenever electrocardiographic studies are shared for the purpose of quality assurance and/or education.*

## **Section 7: A Framework for ECG Laboratories to Achieve the Standards**

The standards outlined in this document provide a framework for facilities to enhance patient care delivery processes which can serve to reduce variation in service and ensure quality patient care.

The availability of these standards allows operators of ECG facilities to use them to modify their processes and procedures in a way that will enhance optimal service delivery. Accepting and adhering to these standards will promote more consistent and appropriate processes and, thereby, enhance quality of services.

**Self-Review:** ECG-based facilities are encouraged to undergo a self-assessment against these standards on a predetermined regularly occurring basis.

## Appendix A: Abbreviations and Definitions:

**Ambulatory ECG Monitoring (AEM):** There are several modalities of testing including ambulatory Holter monitoring of various durations (e.g., 24 hour, 48 hour) and external (loop) event recorders (EER).

**BCLS:** Basic Cardiac Life Support

**Electrocardiogram (ECG):** The process of recording the electrical activity of the heart using 12 leads. Is a non-invasive diagnostic test.

**Exercise ECG Stress Testing (EST):** The process of monitoring the heart rate and rhythm while a patient is exercising (usually on an exercise treadmill).

- Exercise ECG Stress Testing (EST) assesses a patient's ability to tolerate increasing intensities of exercise while electrocardiographic, hemodynamic, and symptomatic responses are monitored for manifestations of myocardial ischemia, electrical instability, or other exertion-related signs or symptoms. EST, if possible, is preferred over pharmacologic testing with its ability to more accurately capture patient's response to exercise. In addition, EST provides an assessment of patient's functional capacity (Mancini et al., 2014).
- Cycle ergometry is an alternative to treadmill testing for patients who have orthopedic, peripheral vascular or neurological limitations that restrict weight bearing. Physiological responses to exercise on a cycle ergometer differ from those obtained on a treadmill. Moreover, maximum oxygen uptake is 5% to 20% lower on a cycle ergometer than on the treadmill. As is the case with treadmill testing, there is a significant degree of error that shall be considered when exercise capacity is estimated from the cycle ergometer work rate.
- Arm exercise testing is a useful alternative for diagnostic testing of patients with lower-extremity impairment caused by vascular, orthopedic, or neurological conditions. In addition, arm ergometry is helpful for performing occupational evaluations in patients whose work primarily involves the arms and upper body. Oxygen uptake during any equivalent submaximal level of arm work exceeds that of leg work. Accordingly, the rate of increase in heart rate and blood pressure responses during arm ergometry is more rapid.
- Metabolic exercise testing (MET) involves use of ventilator-expired gas analysis using computerized metabolic systems which greatly improves both accuracy and reproducibility for assessing cardiopulmonary function compared with indirect estimation of oxygen uptake from work rate.

**CSCT:** Canadian Society of Cardiology Technologists. (<http://www.csct.ca>)

**External (loop) Event Recorder (EER) (Moya et al., 2009):** Is a continuous monitor that records the electrical activity of the heart when the patient activates a button to record the electrocardiogram while they are experiencing symptoms. EER can take different forms:

- A simple event recorder is a real time patient-activated acquisition device that is applied to the chest or hands when a patient experiences symptoms. It is capable of recording a single channel ECG rhythm strip for 30 seconds or up to several minutes. The recording is then downloaded

physically or via telephone to specialized software which produces recordings for review by an ECG technologist who in turn prepares a summary of all reported symptoms and corresponding rhythm strips for interpretation by the physician.

- A loop event recorder is worn continuously like a Holter recorder however captures ECG recordings only when prompted by the patient, usually during symptoms. These recordings capture several minutes before and after activation by the patient.
  - Some loop event recorders are equipped with an analysis algorithm, which is set to automatically activate the memory of the device based on a variety of pre-sets, such as a heart rate that is more rapid than the pre-set, a pause that is longer than the pre-set, or an irregular rhythm that may be AF. The stored information is transferred to a processing station by either land-line or wireless trans-telephonic transmission or direct physical download from the device memory. An ECG technologist processes, analyzes, and collates this information and prepares a report for the reading physician.

**Holter Monitor:** Holter monitoring is the acquisition of a continuous ambulatory electrocardiographic recording of all beats in three or more simultaneous channels, using three to five skin electrodes, for periods of 24, 48, 72 hours, or 7 days, 14 days, or 30 days.

- Patients are provided with a diary and are instructed to record timed symptoms and to activate an event marker on the device at the time of symptoms. These recordings are occasionally pre-analyzed in real time, but most are transferred digitally to a scanning station, and analyzed post-hoc using proprietary arrhythmia recognition algorithms.

**Insertable Cardiac Monitor Recorders (ICM):** Are leadless monitoring devices that record the electrical activity of the heart, that are inserted under the skin for extended periods of time (12 – 24 months) when long-term monitoring is indicated.

- Device manufacturers provide computers/programmers that Registered Nurses (RNs) and/or technologists use to customize the settings on the recorder for each patient in order to capture patient-specific arrhythmias.
- ECG tracings can be completed and transmitted by telephone, or in person by interrogation with the manufacturer's programmer depending on device type.

ICMs are used primarily to exclude cardiac arrhythmias as a cause for symptoms when very long-term monitoring is indicated, or to monitor for atrial fibrillation (AF) recurrence after catheter ablation therapy.

**MET:** Metabolic Stress Test

**RN:** Registered Nurse with the College of Nurses of Ontario

**RPN:** Registered Practical Nurse with the College of Nurses of Ontario

# Appendix B: Indications for Electrocardiographic Examinations

## Indications for 12-lead Electrocardiograms

### 1. Evaluation of new or recurrent signs or symptoms of suspected cardiac disease:

- 1.1. Chest pain of suspected cardiac origin.
- 1.2. Symptoms compatible with heart failure (i.e., exertional fatigue, exercise intolerance, dyspnea at rest or upon exertion, chest discomfort, orthopnea, paroxysmal nocturnal dyspnoea [PND], peripheral edema).
- 1.3. Symptoms suggestive of a primary cardiac rhythm disturbance. Typical symptoms include, for example, palpitations, syncope, and pre-syncope.
- 1.4. Clinical signs suggestive of cardiac disease (i.e., hemodynamic abnormality, pulse rate abnormality, abnormal physical findings on cardiac examination, physical findings suggestive of heart failure).

### 2. Assessment of patients with established cardiovascular disease:

- 2.1. Assessment of patients with known structural heart disease (i.e., ischemic heart disease, ventricular hypertrophy, cardiomyopathy, valvular heart disease, congenital heart disease, pericardial disease).
- 2.2. Periodic cardiac evaluation (yearly) in patients with structural heart disease with no change in their symptoms.
- 2.3. Periodic cardiac evaluation (yearly) in patients with stable cardiac arrhythmia conditions with no change in their symptoms (i.e., atrial arrhythmia, ventricular arrhythmia, premature ventricular contraction [PVC], conduction disease, ventricular pre-excitation, supraventricular tachycardia [SVT]).
- 2.4. Assessment of patients that have a change in symptoms.
- 2.5. Assessment of patients as part of an “annual routine clinical follow-up” (Mancini et al., 2014).
- 2.6. Initial assessment and reassessment of patients with a pacemaker, implantable cardioverter-defibrillator (ICD) or cardiac resynchronization therapy device (CRT).
- 2.7. Initial assessment and reassessment of patients with confirmed or suspected inherited arrhythmia syndromes (i.e., long QT syndrome, short QT syndrome, Brugada syndrome, or Brugada ECG pattern, Catecholaminergic Polymorphic Ventricular Tachycardia [CPVT], idiopathic Ventricular fibrillation, arrhythmogenic right ventricular cardiomyopathy [ARVC]).
- 2.8. Initial evaluation of patients with known arterial disease (i.e., peripheral artery disease, cerebrovascular disease, arterial aneurysmal disease, presence of significant plaque in any vascular bed).
- 2.9. Initial evaluation of patients who will initiate cardiac rehabilitation.
- 2.10. Baseline assessment of patients with existing medical co-morbidities that may lead to cardiac arrhythmic problems in the future (i.e., Sarcoid, Amyloid, Rheumatoid arthritis).

### **3. Screening in asymptomatic patients without established cardiovascular disease:**

- 3.1. Initial evaluation of patients with at least one risk factor for coronary artery disease (i.e., diabetes (<http://guidelines.diabetes.ca/executivesummary/ch23.aspx>), smoking, hyperlipidemia, hypertension, family history of premature coronary artery disease [defined as having a parent who suffered a myocardial infarction before the age of 60 – Reynolds Risk Score]) (Ridker, et al., 2007).
- 3.2. Initial evaluation of patients who want to initiate an exercise program, including athletes (Sharma et al., 2017).
- 3.3. Pre-operative assessment of patients considered to be at increased risk for perioperative cardiovascular morbidity (i.e., high risk surgery such as emergency surgery or major vascular, thoracic or abdominal surgery; history of chronic heart disease; history of chronic heart failure; history of cerebrovascular disease; perioperative treatment with insulin; preoperative serum creatinine > 176 umol/L) (Lee et al., 1999).
- 3.4. Pre-operative assessment of patients undergoing surgeries with moderate (1-5%) or high (>5%) risk for cardiovascular morbidity. High risk surgery includes vascular and cardiac surgery. Intermediate risk surgeries include intraperitoneal or intrathoracic surgery, carotid endarterectomy, head and neck surgery, orthopedic surgery and prostate surgery (Fleisher et al., 2007).
- 3.5. Pre-operative assessment of obese patients (defined as Body Mass Index  $\geq 30/m^2$ ) with at least one (1) cardiac risk factor who are scheduled for surgery (Poirier et al., 2009).
- 3.6. Initial evaluation of patients at elevated risk of vascular disease (i.e., diabetes, renal disease, obesity).
- 3.7. Initial evaluation of patients with pulmonary disease, including those with pulmonary vascular disease (i.e., to assess for right ventricular hypertrophy and/or atrial arrhythmias).

### **4. Electrocardiographic evaluation, follow up and monitoring of drug therapy, post invasive cardiac procedures and/or surgeries:**

- 4.1. Baseline and further periodic assessment of patients who receive medications which are known to cause electrocardiographic changes (i.e., heart rate, PR interval, QRS duration, QT interval).
- 4.2. Follow-up assessment of electrocardiographic changes due to initiation or dose adjustment of medications (i.e., heart rate, PR interval, QRS duration, QT interval).
- 4.3. Baseline assessment of patients who will initiate medications which are known to cause non-arrhythmic cardiac side effects (i.e., LV systolic dysfunction due to anthracycline-based chemotherapy).



## Indications for Ambulatory ECG Monitoring (AEM)

- 1. The most common indications for AEM monitoring are for “symptom-rhythm correlation” and to detect arrhythmias that have diagnostic or prognostic importance, even in the absence of symptoms.** Requirements for this indication include:
  - An **unambiguous** definition of the instant that the symptoms start and stop.
  - The identification on the ECG recording (i.e., time stamp or time indication of the moment the device is activated—“activation time stamp”).
  - A method for recording patient symptoms by either a diary, or an audio communication for symptoms, which is a verbal report (usually by telephone) from the patient to a team member for permanent recording as part of the study.
- 2. Symptoms of syncope and/or palpitations are more typically associated with arrhythmias.** Other transient symptoms such as chest pain, shortness of breath, or presyncope may also warrant AEM; however, these symptoms are less specific for an arrhythmic cause:
- 3. Screening to detect arrhythmias that have diagnostic or prognostic importance, even in the absence of symptoms.** Examples would include screening for ventricular arrhythmias in patients with left ventricular (LV) dysfunction or inherited cardiomyopathies; surveying for atrial fibrillation (AF) in patients with unexplained thromboembolic events; monitoring pharmacologic management, particularly with antiarrhythmic or rate control medication. For this category, and for each abnormality, the following definitions are required:
  - Relative yield (i.e., proportion of patients in whom the arrhythmia is detected);
  - Diagnostic accuracy;
  - Prognostic value; and
  - Therapeutic value (i.e., available treatments that will alter outcomes independently of symptoms).

Categories of arrhythmias that may be considered for the definitions above include atrial and ventricular premature beats, atrial tachycardia, non-sustained ventricular tachycardia (VT), sustained supraventricular tachycardia (SVT), atrial fibrillation or flutter (AF), and sustained VT.

Note: where a diagnosis of symptom-rhythm correlation has been made, or where a monitor has detected an arrhythmia of prognostic or therapeutic usefulness, in general there is NO indication to repeat monitoring at regular intervals unless there is a clear change in patient symptoms or condition to warrant repeat monitoring for the same reasons as above.

The recording of the timing and the nature of the symptoms that occurred at the exact instant (patient activated or not, where symptoms are present) of the ECG recording is especially important for transient symptoms.

AEM for symptom-rhythm correlation generally requires symptoms to be present sufficiently to have a reasonable chance of capturing the symptoms during the recording period. For example, the average interval between symptomatic episodes should be in general no more than twice as long as the monitoring period.

In case of intermittent monitoring, the symptoms should generally be long enough (typically more than 15 or 30 seconds) to allow the monitor to be applied and activated. This requirement does not apply to continuous loop monitoring with automated triggers, provided the software is sufficiently sensitive to detect most, if not all, episodes of pathologic arrhythmia desired to be captured, and that the system is sufficiently specific to avoid excessive numbers of recorded events unrelated to arrhythmia (i.e., environmental noise).

#### 4. Identification of arrhythmic risk:

There are specific instances when AEM monitoring may be recommended for identification of risk in specific populations (Sharma et al., 2017) Special cases in which ambulatory monitoring may be considered include:

- 4.1. Patients with Wolff-Parkinson-White (WPW) to assess the presence of continuous or intermittent pre-excitation.
- 4.2. QT dynamics in patients with long QT syndrome.
- 4.3. ST segment dynamics in patients with myocardial ischemia.
- 4.4. Changes in ST segments in the Brugada syndrome, suspected or proven coronary spasm, short QT syndrome, early repolarization syndrome (Rautaharju, et al., 2009).
- 4.5. Identification of non-sustained ventricular arrhythmias in cardiomyopathies such as hypertrophic, dilated, or ischemic cardiomyopathy (this may influence decisions about defibrillator therapy).
- 4.6. Evaluation of rate response or device function in patients with implanted pacemakers/defibrillators.
- 4.7. Evaluation of ventricular rate dynamics in patients with atrial fibrillation or flutter where good rate control has not yet been established.

Holters are sometimes used to quantify AF burden in order to help assess stroke risk. It is difficult to answer the question "how much atrial fibrillation is too much". Recent studies from Denmark and the ASSERT study may be lowering the bar (**as little as 6 minutes of AF may increase stroke risk**) but to date there are no prospective interventional studies to indicate when therapeutic anticoagulation might be effective in short-lived runs of AF. For that reason, many readers continue to require 30 seconds of AF before reporting it as AF.

In patients being investigated for detection of paroxysmal AF as a contributor to cryptogenic stroke, longer duration monitoring is often required than the current standard of practice for ambulatory monitoring (Gladstone et al., 2014). A minimum of 14 days or longer may be required with a monitor

capable of automatic AF detection. Evidence is evolving that ICMs may be the modality of choice for these patients since detection of any AF may be enough to change therapy to oral anticoagulation.

Since there are no studies indicating the utility of heart rate variability or turbulence in a treatment algorithm, these are not currently indicated.

AEM monitoring is often employed for evaluation of syncope. However, depending on frequency of syncope, the yield for shorter duration AEM monitoring is often very low. Longer duration monitoring and even ICMs are becoming more strongly indicated for syncope of unknown etiology.

### **Determining choice, duration & frequency of monitoring:**

Determination of the ideal duration of monitoring depends on the frequency of patient symptoms. In patients with extremely frequent symptoms, a 48 or 72 hour Holter may be adequate to record the ECG during typical symptoms. In most cases, a more prolonged monitoring period will be necessary (i.e., 14 - data loop monitor). The report should include patient comments when symptoms occur, and whether they were typical of those prompting the test. For patients with more infrequent symptoms, it is probably more cost effective to perform longer duration monitoring rather than repetitive shorter duration monitoring.

The choice of AEM modality must be individualized for the patient and depends in part on whether symptom-rhythm correlation is required, in which case an EER or Holter with patient event activation would be the best choice. If detection of silent, potentially prognostic arrhythmias is required, then continuous Holter monitoring would be best.

Many devices can be used for multiple functions including long-term Holter monitoring and external event recording. These devices may be more convenient and cost effective for AEM laboratories however such combination devices must meet the requirements for each component of their monitoring abilities (i.e., Holter, EER) and patients must be specifically instructed on how to use the device depending on the indications and type of monitoring indicated.

Details of the recommendations are outlined in the AHA/ACC/HRS guideline for the management of patients with atrial fibrillation (January et al., 2014).

### **Indications for Insertable Cardiac Monitor Recorders**

#### **1. An insertable cardiac monitor recorder is indicated for:**

- 1.1 Recurrent and/or unexplained syncope.
- 1.2 Cryptogenic stroke or transient ischemia attack.
- 1.3 Long-term monitoring of minimally symptomatic treated patients for paroxysmal atrial fibrillation recurrences, especially post-pulmonary vein ablation.
- 1.4 Unexplained palpitations or other serious symptoms (e.g., seizures) where a cardiac arrhythmia is suspected and not diagnosable by other means, typically because of a very long duration between events.

## Indications for EST

- 1. Evaluation of patients with suspected or known coronary artery disease: (Gibbons, 2002, Mancini et al., 2014)**
  - 1.1. Patients undergoing initial evaluation with suspected or known coronary artery disease.
  - 1.2. Patients with suspected or known coronary artery disease, previously evaluated, now presenting with significant change in clinical status.
  - 1.3. Evaluation of those age  $\geq 30$  with 2 or 3 anginal criteria, and men and women  $\geq 60$  with 1 of 3 anginal criteria should have non-invasive testing for both diagnostic and prognostic purposes. Additionally, those with 1 of 3 anginal criteria with “low pretest likelihood of CAD” but having other characteristics that would indicate cardiovascular risk should also have non-invasive testing). (Mancini et al., 2014)
  
- 2. Discharge post-cardiac ischemic event:**
  - 2.1. Before discharge post cardiac ischemic event for prognostic assessment, activity prescription, evaluation of medical therapy.
  - 2.2. Early after discharge for prognostic assessment, activity prescription, evaluation of medical therapy, and cardiac rehabilitation (symptom limited; about 14 to 21 days).
  - 2.3. Late after discharge for prognostic assessment, activity prescription, evaluation of medical therapy, and cardiac rehabilitation (symptom limited; about 3 to 6 weeks).
  
- 3. Assessment of patients with valvular or structural heart disease:**
  - 3.1. Assessment of functional capacity, symptomatic responses, and exercise capacity in patients with valvular heart disease (Note that caution is advised with maximal exercise testing in patients with aortic stenosis); and
  - 3.2. Evaluation of exercise capacity in patients with significant structural heart disease and/or congenital heart block.(Gibbons et al., 2002)
  
- 4. Assessment of patients with arrhythmias:**
  - 4.1. Identification of appropriate settings in patients with rate-adaptive pacemakers.
  - 4.2. Evaluation of congenital complete heart block in patients considering increased physical activity or participation in competitive sports.
  - 4.3. Evaluation of patients with known or suspected exercise-induced arrhythmias.
  - 4.4. Evaluation of medical, surgical, or ablative therapy in patients with exercise-induced arrhythmias (including atrial fibrillation).
  - 4.5. Investigation of isolated ventricular ectopic beats in middle-aged patients without other evidence of coronary artery disease.

- 4.6. Investigation of prolonged first-degree atrioventricular block or type I second degree Wenckebach, left bundle-branch block, right bundle-branch block, or isolated ectopic beats in young patients considering participation in competitive sports.
- 4.7. Evaluation of patients with reduced exercise tolerance of uncertain etiology to look for chronotropic incompetence, including evaluation of rate-response adequacy of pacemakers.
- 4.8. Evaluation of dyspnea in atrial fibrillation to look for poor rate-control (January et al., 2014).
- 4.9. Evaluation of any exertional symptoms, including arrhythmic symptoms without suspicion of ischemia, to provide in part an objective evaluation of symptom severity, or of perceived functional limitation and provocation or modification of arrhythmias.
- 4.10. Risk stratification of Wolff-Parkinson-White syndrome or other accessory pathways.

## 5. Other evaluation of patients:

- 5.1. Asymptomatic persons with diabetes mellitus who plan to start vigorous exercise.
- 5.2. Persons with multiple risk factors as a guide to risk-reduction therapy.
- 5.3. Asymptomatic men older than 45 years and women older than 55 years who:
  - Plan to start vigorous exercise (especially if sedentary);
  - Are involved in occupations in which impairment might impact public safety; and
  - Are at high risk for CAD due to other diseases (i.e., peripheral vascular disease and chronic renal failure).

Exercise testing is **NOT** recommended for routine screening of asymptomatic men or women.

For recommended indications for stress echocardiography, please refer to the Cardiac Care Network *Standards for Provision of Echocardiography in Ontario 2015*.

### **Indications for Metabolic Exercise Testing** (Guazzi et al., 2012)

1. Assessment of patients with heart failure who are being considered for heart transplantation to identify the mechanism of exercise-induced dyspnea (cardiac versus pulmonary).
2. Assessment of cardiopulmonary fitness and guiding exercise prescription in cardiac rehabilitation settings.
3. Assessment of patients with pulmonary hypertension, chronic lung diseases, suspected myocardial ischemia, and mitochondrial myopathies.
4. Assessment of patients undergoing procedures considered to be “elevated risk” (Fleisher et al., 2014).

Frequency of testing is primarily determined by the risk profile of the patient. However, recent CCS Guidelines for the Diagnosis and Management of Stable Ischemic Heart Disease states that ‘annual testing may be appropriate even in the absence of symptoms or change in status to ensure that a recent comparator of ECG is available should symptoms change’ (Mancini et al., 2014).



## Appendix C: Standard Exercise Stress Test Protocols

### Bruce Protocol, Standard (3 minute stages)

Stage 0	1.7 mph/0% grade/2 METs
Stage 0.5	1.7 mph/5% grade/3 METs
Stage 1	1.7 mph/10% grade/5 METs
Stage 2	2.5 mph/12% grade/7 METs
Stage 3	3.4 mph/14% grade/10 METs
Stage 4	4.2 mph/16% grade/13 METs
Stage 5	5.0 mph/18% grade/15 METs
Stage 6	5.5 mph/20% grade/18 METs
Stage 7	5.5 mph/22% grade/20 METs

### Bruce Low-Level Protocol (3 minute stages)

Stage 1	1.2 mph/0% grade/2 METs
Stage 2	1.2 mph/3% grade/2.5 METs
Stage 3	1.2 mph/6% grade/3 METs
Stage 4	1.7 mph/6% grade/3.5 METs

### Naughton Protocol

Stage 1	1.2 mph/0% grade/2 METs
Stage 2	2.0 mph/0% grade/2.5 METs
Stage 3	2.0 mph/3.5% grade/3 METs
Stage 4	2.0 mph/7.0% grade/4 METs
Stage 5	2.0 mph/10.5% grade/5 METs
Stage 6	2.0 mph/14.0% grade/6 METs
Stage 7	2.0 mph/17.5% grade/7 METs
Stage 8	3.0 mph/12.5% grade/8 METs
Stage 9	3.0 mph/15.0% grade/9 METs
Stage 10	3.0 mph/17.5% grade/10 METs
Stage 11	3.0 mph/20% grade/11 METs

### General Formula for Calculating Oxygen Consumption and METs on Treadmills

Oxygen utilization (ml/kg/min) = (mph x 2.68) + (1.8 x 26.82 x mph x grade/100) + 3.5.

For example, consider Bruce Stage II at 2.5 mph, 12% grade:

Oxygen utilization = (2.5 x 2.68) + (1.8 x 26.82 x 2.5 x 12/100) + 3.5 = 6.70 + 14.48 + 3.5 = 24.68 ml O<sub>2</sub>/kg/min.

Since 1 MET is 3.5 ml O<sub>2</sub>/kg/min, the METs used in the example would be 24.68/3.5 = 7.05 METs.

## Standard Exercise Stress Test Protocols:

### Definitions of blood pressure responses during exercise:

- Exaggerated exercise systolic BP (Ex-SBP, stage 2): sex-specific, age-predicted systolic BP  $\geq$ 95th percentile during the second stage of exercise;
- Exaggerated exercise diastolic BP (Ex-DBP, stage 2): sex-specific, age-predicted diastolic BP  $\geq$ 95th percentile during the second stage of exercise;
- Elevated recovery systolic BP (Rec-SBP, 3 minutes): sex-specific, age-predicted systolic BP  $\geq$ 95th percentile at the third minute of the recovery phase;
- Elevated recovery diastolic BP (Rec-DBP, 3 minutes): sex-specific, age-predicted diastolic BP  $\geq$ 95th percentile at the third minute of the recovery phase; and
- New-onset hypertension: systolic BP  $\geq$ 140 mm Hg or diastolic BP  $\geq$ 90 mm Hg or use of antihypertensive medications on follow-up (Singh et al., 1999).

**Exercise hypertension** is “defined as a rise in systolic blood pressure during exercise above a threshold, usually between 190 and 220 mm Hg. Some studies suggest that exercise hypertension predicts future arterial hypertension in people with normal resting blood pressure” (Lauer et al., 2008).



## Appendix D: Standard Information Required for ECG-Based Reports

**The Standard ECG-Based Diagnostic Report shall contain the following components:**

- Patient identification (name and date of birth) including contact number for patient;
- Name and/or identifier of laboratory, location, and contact information;
- Indication for the test;
- Referring physician;
- Interpreting physician;
- Confirmed by Dr. [insert name] on [insert date] at [insert time].
- Date, time and duration of the recording;
- Hospital ID and/or Health Card number (as applicable);
- Overall interpretation/summary of findings, including any pertinent positive and negative findings as it relates to the assessment of the presenting issue/reason for study;
- Consistency with the qualitative and quantitative data elements;
- Findings of other significant pathology;
- Relevant comparisons to prior studies or reports as available;
- Examination limitations; and
- Summary statement of findings, including further referral or testing if required.

**The Comprehensive 12-Lead ECG shall contain all components as indicated above as well as the following:**

- Ventricular rate;
- Rhythm and/or rhythm disturbances;
- QRS Axis;
- PR, QRS, QT intervals, including relevant comments on abnormal intervals or marked changes to previous values;
- Interpretation of ST segments, T wave morphology;
- Identification of important diagnostic patterns (i.e., myocardial infarction, ischemia, hypertrophy, electrolyte disturbance, drug toxicity, abnormal pacemaker/defibrillator function) (Hancock et al., 2009; Wagner et al., 2009);
- Name of physician who interpreted the ECG; and
- Date and time at which the interpretation was finalized.

### **Additional Requirements for AEM Reports**

**All AEM reports shall include the components as indicated above and in addition, the following specific information shall be provided:**

- 12-lead ECG;
- Predominant rhythm noted on Holter—average heart rate (heart rate range);
- Basic rhythm(s), minimum/maximum/average heart rate and any unusual rate variability (e.g., due to active vagal tone at night);

- Presence of any atrial arrhythmias including AF—if not sustained (< 30 seconds), consider reporting as non-sustained SVT and include number of episodes and longest duration of SVT, atrial tachycardia, or re-entrant supraventricular tachycardia;
- Presence of any ventricular arrhythmias—if not sustained (< 30 seconds), consider reporting as non-sustained VT and include number of episodes and longest duration of NSVT;
- The number of premature atrial and/or ventricular beats per 24 hours shall be stated;
- Many interpreters will add a qualifier as to whether this represents rare, occasional, or frequent premature beats. There are no specific guidelines to define these qualifiers, but rare typically refers to less than 0.1% (about 200) per 24 hours, occasional is 0.1%-1% (about 200-999 per 24 hours), frequent is 1%-10% (about 1,000-10,000 per 24 hours), and very frequent is >10% (>10,000 per 24 hours);
- Identification of atrial fibrillation (AF) or atrial flutter;
- Caution shall be exercised in over-calling brief episodes of atrial tachycardia (i.e., a few beats) as AF given the implications for stroke prevention with oral anticoagulation. Although there is no consensus on what constitutes non-sustained AF, it is recommended that a minimum duration of 30 seconds of an irregularly irregular rhythm is required to call something AF. There is no current evidence to suggest that 30 seconds of AF absolutely requires anticoagulation in most cases;
- Identification of ventricular arrhythmias such as ventricular tachycardia, torsades de pointes, or ventricular fibrillation;
  - Non-sustained VT is typically 3 or more beats of wide complex ventricular beats >100 bpm, while sustained VT is typically defined as more than 30 seconds in duration.
- Bradyarrhythmias and origin of slowest heart rate (e.g., sinus node dysfunction, Atrioventricular block or other, longest pause, number of pauses >3 seconds in sinus and > 4 seconds in AF and duration of longest pause);
- Summary of symptoms and/or events reported or activated by patient with ECG and whether there is any correlation to rhythm events on the AEM recording;
- Summary and conclusion section including important and relevant findings and comparison to prior recordings where applicable; and
- Representative tracings illustrating abnormalities shall be included or readily available on request.

### **Additional Requirements for EST and MET Reports:**

**All EST and Metabolic Exercise Testing (MET) reports shall include the information as indicated above and in addition, the following specific information shall be provided:**

- Specific exercise protocol used;
- Duration of exercise (with maximal METs attained);
- Percentage of target heart rate attained—submaximal or adequate stress;
- Reason for stopping test and any symptoms that developed during exercise;
- Heart rate response (normal, or evidence of chronotropic incompetence, deconditioning causing rapid rises in sinus rate);
- Blood pressure response (normal, hypertensive, and drop in BP with exercise);
- Presence of ST segment depression or elevation at peak exercise (number of leads);
- Recovery of ST segment abnormalities (within one minute of recovery or prolonged);
- Development of any arrhythmias during exercise;

- Development of any heart block during exercise;
- Summary statement giving probability of significant coronary disease/events;
- Baseline ECG, heart rate, and blood pressure;
- Peak work rate achieved by the patient in METs or VO<sub>2</sub> (specify if estimated or directly measured), peak heart rate and peak blood pressure;
  - Can also express as percentage of target heart rate achieved.
- Abnormal signs or symptoms that occurred during or after the test;
- Appropriate reference values for age and gender, most specifically target heart rate;
- ECG data including at rest, abnormal exercise changes, and return to baseline;
- If ischemia was demonstrated by ECG changes, the time and heart rate at which the changes initially occurred;
- Magnitude (amount of ST depression/elevation) and extent (number of leads) in which ischemic ECG changes are seen;
- If gas exchange measurements were made, peak oxygen uptake (in mL of O<sub>2</sub> per minute and mL of O<sub>2</sub>/kg/min), and the ventilatory threshold (if achieved);
- An overall probability for significant coronary artery disease or events (low, moderate, high);
  - This could be done quantitatively by including an integrated stress test score (such as the Duke Treadmill Score):
    - Duke Treadmill Score = minutes exercised – (4 x angina scale) – (5 x ST segment depression);
    - Angina scale = 0, no angina; 1, non-limiting angina; 2, exercise limiting angina; and Low risk is > + 4, moderate risk + 4 to -11, high risk < -11.
- A summary impression of the findings; and
- Any recommendations for further diagnostic testing.

### **Additional Requirements for ICM Reports**

**All ICM reports shall include the information as indicated above and in addition, the following specific information shall be provided:**

- Transmission date(s);
- A description of the findings of all events transmitted and their clinical significance; and
- A copy of recorder tracings/rhythm strips showing the major findings.

A transmission is a receipt of ICM data by the Arrhythmia Device Clinic. A transmission may contain one or multiple events. Transmissions may take place via direct download at the centre or via remote monitoring.

An event is defined as a discreet, time-stamped recording of cardiac data that may be automatically or manually initiated.

**Cardiac monitor recorder transmissions or groups of transmissions (direct or remote) downloaded at any particular point shall have a final report which includes:**

- A description of the findings of all events within the transmission; and
- Direct and remote monitored transmissions processed and reported in the same manner.

Guidelines on remote monitoring of devices and appropriate turnaround times for off-hour transmissions have been published by the Canadian Cardiovascular Society (Yee et al., 2013), and provide further details on requirements of a remote monitoring program.

## Critical Findings

### ECG critical findings include the following:

- High grade Atrioventricular (AV) block;
- Extreme bradycardia (< 30 bpm);
- Atrial fibrillation (AF) associated with ventricular pre-excitation;
- Ventricular tachycardia (VT), or torsades de pointes;
- Pacemaker malfunction (e.g., loss of capture, over-sensing, under-sensing);
- Acute myocardial infarction (ST elevation);
- ECG patterns suggestive of a severe metabolic derangement (e.g. hypo or hyperkalemia); or
- Severe QT prolongation (corrected QT > 500 msec).

### AEM critical findings include the following:

- Prolonged sinus pauses greater or equal to 10 seconds;
- Pre-excited atrial fibrillation;
- Sustained ventricular tachycardia (greater than 30 seconds and at a rate equal to or greater than 150 bpm);
- Episodes of non-sustained polymorphic VT, torsades de pointes, VF;
- Bradycardia with heart rate less than 30 bpm for >1 minute, especially if not nocturnal;
- Pacemakers/automated implantable cardioverter-defibrillator malfunction;
- Alternating bundle branch block, or second degree AV block, Mobitz II on a background of right bundle branch block (RBBB) and left anterior fascicular block (LAFB) on 12-lead ECG;
- Complete heart block with heart rate < 40 bpm;
- Transient ST elevation of 2mm or greater; or
- Long QTc of 500ms or greater.

### EST critical findings include the following:

- ST elevation;
- Early, severe ST depression;
- Development of unstable arrhythmia(s);
- A significant and symptomatic drop in blood pressure (30mm mg);
- Non-sustained torsades de pointes, VT, or VF; or
- Significant Bradyarrhythmias (high grade AV block).

## 12-lead ECG Sample Report

**Sample report of an interpreted, physician-confirmed 12-lead electrocardiogram (ECG)**

**1** Male

**2** **3**

**4** 23-FEB-2013 20:07:25

**5** 154 BPM

**6** \* 68 ms

**7** 238.977 ms

**8** QTc 94

**9** Atrial flutter with 2:1 A-V conduction

**10** Left axis deviation

**11** Left ventricular hypertrophy with repolarization abnormality

**12** Abnormal ECG. Compared to the previous ECG on JAN 3 2013 (10:05:05AM), atrial flutter is a new diagnosis. Confirmed by JOHN SMITH, MD on 2/24/2013 8:29:54 PM

**13** Confirmed By: JOHN SMITH, MD

**6** Indication: Elevated pulse

**7** Referred by: DEREK JONES, MD

**8** Time and date of ECG acquisition

**9** Paper speed, voltage scale, filter settings

**10** Clinical indication (preferred but not mandatory)

**11** Referring physician

**12** Ventricular rate, PR, QRS, QT, corrected QT intervals\*

**13** Rhythm diagnosis

**14** Description of pertinent abnormal ECG findings

**15** Summary statement of ECG interpretation, with comparison to previous ECG's, if applicable

**16** Date and time of confirmation.

**17** Name of physician who confirmed the ECG interpretation

\* Computer-derived measurements of ventricular rate, PR axis, and/or intervals (PR, QRS, QT, QTc) may be inaccurate. Discrepancy between the derived and actual measurements should be discussed in the ECG interpretation section.

25mm/s 10mm/mV 150Hz

## Holter Monitor Sample Report

Confirmed by Dr. [insert name] on [insert date] at [insert time].

REASON for STUDY				
Premature ventricular complex				
Indications:				
BEAT COUNTS		HEART RATES		
QRS complexes: 181378		Minimum: 40	at: 03:38:33	09-Nov-2013
Paced: 0		Maximum: 122	at: 08:53:48	08-Nov-2013
Ventricular ectopics: 41941	23% of QRS complexes	Average: 59		
Supraventricular ectopics: 25	< 1% of QRS complexes			
VENTRICULAR ECTOPY				
Isolated: 41265	8 beats LONGEST at:	109bpm	13:42:22	08-Nov-2013
Couplets: 41	8 beats FASTEST at:	109bpm	13:42:22	08-Nov-2013
Runs: 195				
Total beats: 594				
Bigeminal: 36127				
SUPRAVENTRICULAR ECTOPY				
Isolated: 23				
Couplets: 1	beats FASTEST at:	bpm		
Runs: 0				
Total beats: 0				
Longest RR: 1.760	sec at:	03:31:57	09-Nov-2013	
			Acq duration: 47:59	
INTERPRETATION				
The rhythm was sinus with intervals within normal limits.				
Nonspecific ST-T wave abnormalities noted.				
There were very rare premature atrial beats.				
There were frequent (23%) mostly monomorphic premature ventricular beats and fusion beats.				
There were 195, 3-8 beat runs of accelerated idioventricular rhythm/tachycardia at rates of 64-109bpm.				
Five markers with no symptoms reported corresponded to sinus rhythm at rates of 55-90 bpm with premature ventricular beats in a bigeminy pattern.				
Findings:				
Sinus rhythm				
Premature atrial complex				
Premature ventricular and fusion complexes				
Accelerated idioventricular rhythm				
Ventricular tachycardia				
READING MD:	<input type="text"/>			

## Appendix E: Facilities and Equipment

**ECG-based testing facilities performing additional modalities shall also provide the following:**

**AEM: laboratories shall have a digitally-based acquisition system capable of display, printing, and storage of AEM strips.**

Modern frequency modulated, digitally-based systems avoid all of the artifacts of the older systems and now have hard drive or flash card-based storage that allows for signal storage and transfer without loss of fidelity. Modern digital equipment utilizes proprietary software-based playback systems for reviewing and editing strips obtained from AEM. Such software will also have automated algorithms to calculate a number of standard measurements.

**AEM: laboratories shall be able to calculate the following:**

- Number of QRS complexes;
- Average, and range of heart rate;
- Premature ventricular contraction (PVC) and premature atrial contraction (PAC) detection; and
- Pause, basic supraventricular tachycardia (SVT) and VT detection.

More advanced applications include the measurement of ST segment shifts, heart rate variability, and T wave alternans, which may not be present on most standard systems. More sophisticated event monitors may also have automatic algorithms for detection of AF, VT and other specific arrhythmias. While these may aid significantly in physician interpretation, each AEM laboratory shall calibrate and ensure the accuracy of automated measurements and arrhythmia detection.

**ICM: Equipment shall be capable of full disclosure such that the entire duration of the recording can be viewed for interpretation and stored in a manner to enable retrieval at a later date.**

- Remote monitoring of ICMs shall be maintained by a secure web-based portal that will send transmissions to the device clinic in accordance with provincial guidelines for medical records.

**ICM: facilities shall maintain a database to track all ICMs inserted/implanted and followed at the centre.**

**EST: laboratories require the following additional items in the procedure room:**

- Treadmill/bicycle ECG monitoring;
- Vital signs monitor for blood pressure, heart rate and oxygen saturation monitoring;
- Medical oxygen;
- Intravenous equipment;
- Emergency cart containing a defibrillator, airway management equipment, medications for urgent resuscitation and other related equipment;
- A means of rapidly calling for help with an unstable patient (e.g., phone, intercom, arrest buzzer); and
- A bed capable of being moved and positioned appropriately for resuscitation.

**EST: Treadmills used for EST shall have the following:**

- Electrically driven and able to accommodate body weights up to at least 157.5 kg (350 lbs.);
- Wide range of speeds, from 1.6 km/h (1 mph) to at least 12.8 km/h (8 mph);
- Variety of electronically controlled elevation settings ranging from no elevation to 20% elevation;
- Treadmill platform which is a minimum of 127 cm (50 in) long and 40.64 cm (16 in) wide;
- Side platforms to allow the patient to adapt to the moving belt before fully stepping onto it;
- Padded front rail and at least one side rail. Patient shall be discouraged from holding the handrails as much as possible, because doing so decreases the metabolic cost of the work rate;
- Emergency stop button that is easily visible and readily accessible to the staff and the patient when needed; and
- Ability to estimate the metabolic cost of the treadmill work rate from speed and grade by use of standardized equations (e.g., American College of Sports Medicine, <http://certification.acsm.org/metabolic-calcs>) (Thompson, 2010).

**EST: Cycle Ergometers used for EST shall have the following:**

- The capability to adjust work intensity by varying the resistance and cycling rate and to calculate the work rate in watts or kilopond-meters per minute (kpm/min);
- If mechanical brakes, the ability to maintain a specified cycling rate to keep the work rate constant. If electronic brakes, the ability to adjust internal resistance to maintain specified work rates according to the cycling rate;
- The capability to adjust the work rate in increments either automatically or manually;
- Handlebars and a seat that adjusts for height. At the ideal seat height, the knee should be slightly flexed at full extension;
- Adaptable pedal grips; and
- Appropriately sized meters, dials, or digital displays (i.e., for RPMs) that are placed for easy reading.

**EST: Cycle arm ergometers used for EST shall have the following:**

- Mechanical or electronic brakes; and
- Sustainable cycling speeds of 60 to 75 rpm.

**EST: Calibration of the treadmill and cycle ergometer (both leg and arm) shall be performed and recorded on a monthly basis according to manufacturer's specifications.**

**EST: Laboratories providing EST shall have a digitally-based acquisition system capable of:**

- Displaying, printing, and storing ECG stress testing strips; and
- Recall of EST in its entirety for review and interpretation.

**MET: Equipment used for metabolic exercise testing shall have the capability to assess the following:**

- The peak oxygen uptake;
- Ventilatory threshold;
- The relationship between ventilation and carbon dioxide production ( $V_E/V_{CO_2}$  slope);
- The partial pressure of end-tidal carbon dioxide; and
- Oxygen uptake kinetics.



## Appendix F: Medical Staff Competency Guidelines

### ECG

In Ontario, ECGs are interpreted by a variety of physicians with different training backgrounds, including: cardiologists, general internists, emergency room physicians, family physicians, and anesthesiologists. In Canada, there is no national certifying exam to assess one's proficiency in ECG interpretation, although such exams do exist in certain provinces (e. g. Alberta). As a result, the competence of the ECG reader is solely dependent on his or her training and additional efforts spent in mastering this skill.

The American Heart Association / American College of Cardiology / American College of Physicians – American Society of Internal Medicine have published a list of cognitive skills needed to competently interpret ambulatory ECGs (Salerno et al., 1999, Surawicz et al., 2009) . A list of electrocardiographic diagnoses that must be readily recognized by a competent ECG reader is also outlined in the publication. Based on consensus opinion, the ACC/AHA recommends that a physician must interpret **at least 500 ECGs** under the supervision of an “expert” electrocardiographer in order to be competent for independent ECG interpretation. The reader is referred to this document for details (Kadish et al., 2001).

In general, a physician shall possess the following knowledge when interpreting ECGs:

- Understand and recognize the basic pathophysiology of electrocardiographic abnormalities;
- Recognize the process of ECG acquisition to determine whether an artifact is present and to judge whether the overall quality of the ECG is sufficient for accurate interpretation; and
- Recognize the sensitivity and specificity of the ECG for the diagnosis of common and high-risk clinical disorders.

### EST

In Canada, there is no national certifying exam to assess one's proficiency in EST interpretation. As a result, the competence of the EST reader is solely dependent on his/her training and additional efforts spent in mastering this skill. The physician is typically a cardiologist or general internist with additional training in cardiology, with specific rotations or training in ECG EST interpretation.

Cognitive skills needed to competently supervise EST are outlined in the guidelines (Rodgers et al., 2000) and include knowledge of the following:

- Indications for exercise testing;
- Alternative physiological cardiovascular tests;
- Contraindications, risks, and risk assessment of testing;
- Recognition and treatment of complications of exercise testing;
- Cardiopulmonary resuscitation and successful certification of an accredited course in advanced cardiovascular life support (ACLS) and re-certification annually as required;
- Various exercise protocols and indications for each;
- Basic cardiovascular and exercise physiology including:
  - Hemodynamic response to exercise;
  - Cardiac arrhythmias with the ability to recognize and treat serious arrhythmias;

- Cardiovascular drugs and how they can affect exercise performance, hemodynamics, and the ECG; and
- The effects of age and disease on hemodynamic and ECG responses to exercise.
- Principles and details of exercise testing, including proper lead placement and skin preparation; and
- End points of exercise testing and indications to terminate exercise testing.

Cognitive skills needed to competently interpret exercise tests have been outlined in the guidelines (Rodgers et al., 2000) and include appropriate knowledge of:

- Specificity, sensitivity, and diagnostic accuracy of exercise testing in different patient populations;
- How to apply Bayes' theorem to interpret test results;
- Electrocardiography and changes in the ECG that may result from exercise, hyperventilation, ischemia, hypertrophy, conduction disorders (Surawicz, et al., 2009), electrolyte disturbances, and drugs;
- Conditions and circumstances that can cause false-positive, indeterminate, or false-negative test results;
- The prognostic value of exercise testing;
- Alternative or supplementary diagnostic procedures to exercise testing and when they should be used; and
- The concept of metabolic equivalent (MET) and estimation of exercise intensity in different modes of exercise.

## References

- Bailey, J. J., Berson, A. S., Garson, A. Jr., et al. (1990). Recommendations for standardization and specifications in automated electrocardiography: bandwidth and digital signal processing. A report for health professionals by an ad hoc writing group of the Committee on Electrocardiography and Cardiac Electrophysiology of the Council on Clinical Cardiology, American Heart Association. *Circulation*, 81(2): 730-739.
- Canadian Association for Accreditation of Ambulatory Surgery Facilities. Criteria for Accreditation of Ambulatory Surgery Facilities. Retrieved April 2014, from <http://caaasf.org/downloads/Criteria.pdf>.
- Canadian Medical Association Journal. October 15, 1995. 153:8
- Choosing Wisely Canada. (2014). *Choosing Wisely Canada*. Retrieved April 2014, from <http://www.choosingwiselycanada.org>.
- Clinical Guidelines by Consensus, The Society for Cardiological Science and Technology, British Cardiovascular Society, Feb 2010, Reviewed Feb 2013.
- Fleisher, L. A., Beckman, J. A., Brown, K. A., et al. (2007). ACC/AHA 2007 Guidelines on perioperative cardiovascular evaluation and care for non-cardiac surgery. Executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 2002 Guidelines on Perioperative Cardiovascular Evaluation for Non-cardiac Surgery). *Circulation*, 116(4): 418-500.
- Gibbons, R. J., Balady, G. J., Timothy, B. J., et al. (2002). ACC/AHA 2002 guideline update for exercise testing: summary article: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Update the 1997 Exercise Testing Guidelines). *Circulation*, 106(14): 1883-1892.
- Gladstone, D. J., Spring, M., Dorian, P., et al. (2014). Atrial fibrillation in patients with cryptogenic stroke. *The New England Journal of Medicine*, 370(26): 2467-2477.
- Guazzi, M., Adams, V., Conraads, V., et al. (2002). Clinical recommendations for cardiopulmonary exercise testing data assessment in specific patient populations. *Circulation*, 126(18): 2261-2274.
- Hancock, E. W., Deal, B. J., Mirvis, D. M., Okin, P., Kligfield, P., & Gettes, L. S. (2009). AHA/ACCF/HRS recommendations for the standardization and interpretation of the Electrocardiogram. Part V: electrocardiogram changes associated with cardiac chamber hypertrophy: a scientific statement from the American Heart Association Electrocardiography and Arrhythmias Committee, Council on Clinical Cardiology; the American College of Cardiology Foundation; and the Heart Rhythm Society: Endorsed by The International Society for Computerized Electrocardiology. *Circulation*, 119(10): e251-e263.
- January, C. T., Wann, L. S., Alpert, J. S., et al. (2014). 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: A report of the American College of Cardiology/American Heart

Association Task Force on Practice Guidelines and the Heart Rhythm Society. *Journal of the American College of Cardiology*, 64(21): e1-e76.

Kadish, A., Buxton, A.E., Kennedy, H.L., et al. (2001). ACC/AHA clinical competence statement on electrocardiography and ambulatory electrocardiography: a report of the ACC/AHA/ACP–ASIM Task Force on Clinical Competence (ACC/AHA Committee to Develop a Clinical Competence Statement on Electrocardiography and Ambulatory Electrocardiography). Endorsed by the International Society for Holter and Noninvasive Electrocardiology. *Journal of the American College of Cardiology*, 38(7): 2091-2100.

Kligfield, P., Gettes, L. S., Bailey, J. J., et al. (2007). AHA/ACCF/HRS recommendations for the standardization and interpretation of the electrocardiogram. Part I: the electrocardiogram and its technology: a scientific statement from the American Heart Association Electrocardiography and Arrhythmias Committee, Council on Clinical Cardiology; the American College of Cardiology Foundation; and the Heart Rhythm Society. Endorsed by the International Society for Computerized Electrocardiology. *Circulation*, 49(10): 1109-1127.

Lauer, M. S., Miller, T. D. (2008). The exercise treadmill test: estimating cardiovascular prognosis. *Cleveland Clinic Journal of Medicine*, 7(6): 424-430.

Lee, T. H., Marcantonio, E. R., Mangione, C. M., et al. (1999). Derivation and prospective validation of a simple index for prediction of cardiac risk of major non-cardiac surgery. *Circulation*, 100(10): 1043-1049.

Mancini, J., Goesselin, G., Chow, B., et al. (2014). Canadian Cardiovascular Society guidelines for the diagnosis and management of stable ischemic heart disease. *Canadian Journal of Cardiology*, 30(8): 837-849.

Mason, J. W., Hancock, E. W., & Gettes, L. S. (2007). AHA/ACCF/HRS recommendations for the standardization and interpretation of the electrocardiogram. Part II: electrocardiography diagnostic statement list: a scientific statement from the American Heart Association Electrocardiography and Arrhythmias Committee, Council on Clinical Cardiology; the American College of Cardiology Foundation; and the Heart Rhythm Society. Endorsed by The International Society for Computerized Electrocardiology. *Circulation*, 115(10): 1325-1332.

Moya, A., Sutton, R., Ammirati, F., Blanc, J.J., Brignole, M. (2009) European Heart Rhythm Association (EHRA), Heart Failure Association (HFA), and Heart Rhythm Society (HRS) Guidelines for the diagnosis and management of syncope: The Task Force for the Diagnosis and Management of Syncope of the European Society of Cardiology (ESC). *European Heart Journal*, 30(21), 2631–2671.

Myers, J., Arena, R., Franklin, B., et al. (2009). Recommendations for clinical exercise laboratories: a scientific statement from the American Heart Association. *Circulation*, 119(24): 3144-3161.

Ontario Health Technology Assessment Series (2016) ;Sept. Vol.16: No.TBA:1-56.

Poirier, P., Alpert, M. A., Fleisher, L. A., et al. (2009). American Heart Association Obesity Committee of Council on Nutrition, Physical Activity and Metabolism, Council on Cardiopulmonary Perioperative and Critical Care, Council on Cardiovascular Surgery and Anesthesia, Council on Cardiovascular Disease in the Young, Council on Cardiovascular Nursing, and Council on Clinical Cardiology. Cardiovascular evaluation

and management of severely obese patients undergoing surgery: a science advisory from the American Heart Association. *Circulation*, 120(1): 86-95.

Rautaharju, P. M., Surawicz, B., Gettes, L. S., et al. (2009). AHA/ACCF/HRS recommendations for the standardization and interpretation of the electrocardiogram. Part IV: the ST segment, T and U waves, and the QT interval: a scientific statement from the American Heart Association Electrocardiography and Arrhythmias Committee, Council on Clinical Cardiology; the American College of Cardiology Foundation; and the Heart Rhythm Society. Endorsed by the International Society for Computerized Electrocardiology. *Circulation*, 119(10): e241-250.

Ridker, P. M., Buring, J. E., Rifai, N., et al. (2007). Development and validation of improved algorithms for the assessment of global cardiovascular risk in women: the Reynolds Risk Score. *JAMA*, 297(6): 611-619.

Rodgers, G. P., Ayanian, J. Z., Balady, G., et al. (2000). American College of Cardiology/American Heart Association clinical competence statement on stress testing: a report of the American College of Cardiology/American Heart Association/American College of Physicians–American Society of Internal Medicine Task Force on Clinical Competence. *Journal of the American College of Cardiology*, 36(4): 1441–1453.

Salerno, S. M., Alguire, P. C., Waxman, H. S. (2003). Training and competency evaluation for interpretation of 12-lead electrocardiograms: recommendations from the American College of Physicians. *Annals of Internal Medicine*, 138(9): 747-750.

Singh, J. P., Larson, M. G., Manolio, T. A., et al. (1999). Blood pressure response during treadmill testing as a risk factor for new-onset hypertension: the Framingham Heart Study. *Circulation*, 99(14): 1831-1836.

Sharma, S., Drezner, J.A., Baggish, A., et al. (2017) International Recommendations for Electrocardiographic Interpretation in Athletes. *JACC* 69 (8):1057-1075.

Surawicz, B., Childers, R., Deal, B. J., et al. (2009). AHA/ACCF/HRS recommendations for the standardization and interpretation of the electrocardiogram. Part III: intraventricular conduction disturbances: a scientific statement from the American Heart Association Electrocardiography and Arrhythmias Committee, Council on Clinical Cardiology; the American College of Cardiology Foundation; and the Heart Rhythm Society. Endorsed by the International Society for Computerized Electrocardiology. *Circulation*, 119(10): e235-240.

Thompson, W. R., Gordon, N. F., Pescatello, L. S. American College of Sports Medicine. (2010). *ACSM's guidelines for exercise testing and prescription*. Philadelphia: Wolter Kluwer/Lippincott Williams & Wilkens.

Wagner, G. S., Macfarlane, P., Wellens, H., et al. (2009). AHA/ACCF/HRS recommendations for the standardization and interpretation of the electrocardiogram. Part VI: acute ischemia/infarction: a scientific statement from the American Heart Association Electrocardiography and Arrhythmias Committee, Council on Clinical Cardiology; the American College of Cardiology Foundation; and the Heart Rhythm Society. Endorsed by the International Society for Computerized Electrocardiology. *Circulation*, 119(10): e262-270.

Yee, R., Verma, A., Beardsall, M., et al. (2013). Canadian Cardiovascular Society/Canadian Heart Rhythm Society joint position statement on the use of remote monitoring for cardiovascular implantable electronic device follow-up. *Canadian Journal of Cardiology*, 29(6): 644-651.