CARDEA ASSOCIATES, INC.

CardeaScreen™ ECG Interpretation Criteria

Resting ECG Analysis System

Model CS-2020

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Table of Contents

1 Introduction

2.1 Indications for Use

CardeaScreen records and measures a resting ECG from the adult and pediatric (age ≥ 14) body surface. It provides automatic ECG interpretations which are identified as "unconfirmed" by the product until they have been over-read and confirmed by a clinician.

CardeaScreen is intended for use on apparently healthy individuals and on symptomatically stable patients with known or potential cardiac conditions.

This device is intended for use under the direct supervision of a licensed health care clinician.

2.2 Clinician's Responsibility

Not all cardiac conditions can be detected by an ECG and many potentially detectable conditions are not always present, or may be transitory and not present in a specific ECG. The symptoms, physical exam, patient / family history and additional information are critical to the clinician's overall assessment of a patient's cardiac health. Such information should not be ignored because an ECG appears normal.

It is the clinician's responsibility to ensure proper ECG collection, review and interpretation and ultimately make a diagnosis of the individual's cardiac health and/or risk of cardiac events.

2.3 Contraindications

- CardeaScreen is not intended for use in acute or emergent care, or in surgical or critical care units, or for monitoring vital signs.
- It is not appropriate for patients with pacemakers or patients presenting with acute symptoms that could be emergent.
- It should not be used with patients who are tachycardic (HR>100bpm), unconscious, delirious, confused, have had recent head injury, have chest pain, or possible myocardial infarction.
- It is not intended to be used during transport.

2 ECG Interpretation Criteria

The system uses the measurements determined in the automatic ECG processing to evaluate each possible cardiac condition, following the criteria listed in the table below. These criteria have been compiled based upon:

- Criteria summarized in Uberoi et al, Interpretation of the Electrocardiogram of Young Athletes, Circulation 2011, 124:746 – 757, and the associated extensive references.
- Additional clinical references, as provided below.

Some of these cardiac conditions are abnormal and are know to be associated with increased patient risk. The detection of any of these conditions in a patient ECG triggers a legend displayed by the CardeaScreen device on the ECG:

"Unconfirmed
The ECG findings require further evaluation before participation in competitive sport".

This legend is added to the ECG display for those conditions listed below with the summary action "Recommend Review" and reflects an unconfirmed abnormal ECG.

The remaining lower risk cardiac conditions are important information for the physician in the overall patient risk assessment and may be very important in the context of the patient physical exam and family history. These conditions are listed below with the summary action "Report" but do not trigger the recommendation for further evaluation. Records with only these conditions are labeled as: "**Unconfirmed Normal ECG"**.

All detected cardiac condition statements added to the ECG are defined in the table below using a bold courier font, e.g.: **"Atrial Fibrillation"**

The following requirements state the ECG criteria associated with each diagnostic statement.

Diagnostic Condition	Requirement and Device Response	Clinical References
Heart Rate	The system shall determine the average Heart Rate (HR) HR > 95: **"High HR: XX Recommend re-test after resting"** HR < 30: **"Bradycardia HR: XX"** and Recommend Review.	Yusuf, S. and Camm, A. J. Deciphering the sinus tachycardias. Clinical Cardiology, 2005; 28: 267–276. doi: 10.1002/clc.4960280603
RAA	Right Atrial Abnormality P wave amplitude in V5, aVF or V2 > 250 µV **"RAA lead: XX µVolts"** Recommend Review.	Kaykha A, Myers J, Desser KB, et al. The prognostic importance of isolated P-Wave abnormalities. Clin Cardiol. 2010 Jun;33(6):E87-93. PubMed PMID: 20552614.
LAA	Left Atrial Abnormality V1 ≤ -100 µV AND area of negative pulse > 46 mm-msec AND P-wave terminates in a negative phase. **"LAA V1: XX µVolts, Area: YY mm-msec"** Recommend Review.	Kaykha A, Myers J, Desser KB, et al. The prognostic importance of isolated P-Wave abnormalities. Clin Cardiol. 2010 Jun;33(6):E87-93. PubMed PMID: 20552614.

Flutter	Atrial Flutter 200 bpm < Atrial heart rate < 460 bpm AND P amplitude > 100 µV in lead aVF AND RR (time interval between two beats) standard deviation > 15% of the record average. NOTE: Respiration causes rhythmic increases and decreases of HR. The RR standard deviation should be computed after the removal of rhythmic variability. "**Atrial Flutter**" Recommend Review.	
A.Fib	Atrial Fibrillation No P-waves AND RR standard deviation > 15%. "**Atrial Fibrillation**" Recommend Review.	
Pause	Atrial Pause RR interval > 40% of the average RR intervals. "**Atrial Pause**" Report.	

PAC	Premature Atrial Contraction RR interval < 60% of the average RR intervals. **"Premature Atrial Contraction"** Report.	
Erratic HR	Erratic Heart rate RR standard deviation > 15% and NOT Flutter **"Erratic Sinus"** Report.	
Long PR	Time interval between the onset of P and the isoelectric (Q) point. PR > 300 msec. **"Anomalous PR Interval: XX msec"** Recommend Review.	Pfeufer A, van Noord C, Marciante K et al. Genome-wide association study of PR interval. Nat Genet. 2010 February; 42(2): 153–159. Ramirez A, S Schildcrout J, Blakemore D, et al. Modulators of normal ECG intervals identified in a large electronic medical record. Heart Rhythm. 2011 February; 8(2): 271–277. http://biostat.mc.vanderbilt.edu/wiki/Main/ECGPredictionInterval
Long QRS	QRS duration > 125 msec **"QRS Dur: XX msec"** Recommend Review.	Desai AD, Yaw TS, Yamazaki T, et al. Prognostic Significance of Quantitative QRS Duration. Am J Med. 2006 Jul;119(7):600-6. Bongioanni S, Bianchi F, MigliardiA,et al.Relation of QRS duration to mortality in a community-based cohort with hypertrophic cardiomyopathy.Am J Cardiol. 2007 Aug 1;100(3):503-6. Epub 2007 Jun 13. http://biostat.mc.vanderbilt.edu/wiki/Main/ECGPredictionInterval

Ectopy	Narrow Ectopic Beats: Non-dominant beat with QRS > dominant beat ≤ 120 msec. "**Ectopy present – QRS Duration: XX**" Report. Wide Ectopic Beats: Wide Complex Ectopy: Non-dominant beat(s) having a QRS duration > 120 msec. Single beat: "**Wide complex ectopy present – QRS Duration: XX**" Report. Two or more: "**Wide complex ectopy present – QRS Duration: XX**" Recommend Review. Polymorphic Wide Complex Ectopy: Two or more wide complex non-dominant beats associated with different beat classes (i.e. not the same morphology) "**Polymorphic wide complex ectopy present**" Recommend Review.	Engel G, Cho S, Ghayoumi A, Yamazaki T, et al. Prognostic significance of PVCs and resting heart rate. Ann Noninvasive Electrocardiol. 2007 Apr;12(2):121-9.

Axis Deviation	Deviation is computed from the angle defined by the net excursion (maximum – minimum) in the frontal plane from leads I & aVF. Left Axis Deviation: -135 degrees < QRS Axis < -30 degrees "**Left Axis Deviation: XX°**" Recommend Review. Right Axis Deviation: QRS Axis > 115 degrees "**Right Axis Deviation: XX°**" Recommend Review. Gross Congenital Deviation: -135 degrees < QRS Axis ≥ -180 "**Gross congenital deviation: XX°**" Recommend Review.	

LBBB	Left Bundle Branch Block (A): QRS duration > 120 msec AND In V2: (Area Q) / (Area R + Q) > 0.95 (Predominantly Q) AND T Amp V5 / T Amp V2 < 0.45 AND duration of Q or S in V2 > 80 msec AND Q Amp in V5 = 0 AND NO WPW Or (B): QRS duration > 115 msec AND QRS net amplitude < 0 in V2 AND NO WPW AND S duration ≥ 80 msec in V2 AND No Q is present in V5 AND R duration ≥ 60 msec in V5 **AND** **[**(QRS area ratio > 0.25 in V5 AND R duration ≥ 100 msec in V5 AND QRS duration ≥ 160 msec) **OR** (QRS duration ≥ 140 msec AND R duration > 85 msec in V5) **OR** (QRS duration ≥ 120 msec AND R duration > 85 msec in V5 AND QRS area ratio > 0.4 in V5)**]** Note: QRS area ratio is defined as the ratio of the QRS integral to the area of a rectangle defined by QRS duration and the peak positive amplitude. "**LBBB**" Recommend Review.	Strauss D, Selvester R, Wagner G. Defining Left Bundle Branch Block in the Era of Cardiac Resynchronization Therapy. American Journal of Cardiology. 2011;107: 927-934 DOI: 10.1016/j.amjcard.2010.11.010 Breithardt G and Breithardt O. Left Bundle Branch Block, an Old–New Entity. Open Jour Cardiovasc. Trans. Res. 2012; 5:107–11

RBBB	Right Bundle Branch Block (A): QRS duration > 115 msec AND **[**(S Dur in V5 > 60 msec) OR (RSR' in V2 AND T amp in V1 < -150 µV)**]** AND (RSR' waveform in V2 OR R duration in V2 > 40 msec) AND (T amp in V1 OR V2 < -100 µV) AND NO WPW Or (B): **[(**R amp > 100 µV in V2 AND R Duration > 20 msec in V2 AND No S in V2) **OR** (R' amp > 100 µV in V2 AND R' duration > 20 msec in V2 AND No S' in V2)**]** **AND** **[**(QRS duration ≥ 115 msec AND S duration ≥ 40 msec in V5 AND R duration < 100 msec in V5 AND QRS integral > 0 (ie., positive) in V2 AND V2 does not terminate in S or S') **OR** (QRS duration > 105 msec AND S duration ≥ 60 msec in V5 AND R duration > 60 msec in V2 AND QRS integral > 0 (ie., positive) in V2)**]** **AND** T amp in V1 OR V2 < -100 µV AND NO WPW "**RBBB**" Recommend Review: QRS Dur ≥ 120 msec Report: QRS Dur < 120 msec	Kim J, Noseworthy P, McCarty D, et al. Significance of Electrocardiographic Right Bundle Branch Block in Trained Athletes. American Journal Cardiology. 2011;107(7): 1083-1089. DOI: 10.1016/j.amjcard.2010.11.037 Peters S, Trümmel M, Koehler B. Special features of right bundle branch block in patients with arrhythmogenic right ventricular dysplasia. International Journal of Cardiology, http://dx.doi.org/10.1016/j.ijcard.2011.09.070

icRBBB	Incomplete Right Bundle Branch Block (A): QRS duration < 110 msec AND S duration > 20 msec in V5 AND RSR' waveform in V2 AND Not RBBB AND NO WPW Or (B): **[(**R amp > 100 µV in V2 AND R Duration > 20 msec in V2 AND No S in V2) **OR** (R' amp > 100 µV in V2 AND R' duration > 20 msec in V2 AND No S' in V2)**]** **AND** **(**QRS duration > 90 msec AND QRS duration < 120 msec AND S duration ≥ 40 msec in V5) "**ICRBBB**" Report.	
WPW	Wolff, Parkinson, White QRS duration > 110 msec AND Delta wave present (slope break ratio > 5) AND (PR interval ≤120 msec OR Q – Poff interval ≤ 40 msec) AND R – Q interval > 60 msec "**WPW**" Recommend Review.	Pappone C; Radinovic A, Santinelli V. Sudden Death and Ventricular preexcitation: Is it Necessary to Treat the Asymptomatic Patients? Current Pharmaceutical Design,2008;14, Number 8, 762-765(4). Pappone C, Santinelli V, Rosanio S, et al. Usefulness of invasive electrophysiologic testing to stratify the risk of arrhythmic events in asymptomatic patients with Wolff-Parkinson-White pattern: results from a large prospective long-term follow-up study. J Am CollCardiol. 2003 Jan 15;41(2):239-44.

HCM Q-Waves	Q-Waves diagnostic of HCM in Leads I, V4, V5 or aVF Age < 40 AND No WPW AND NO LBBB AND (Q amp < -350 µV OR Q duration ≥ 40 msec) "**Diagnostic Q-Waves: Lateral Inferior**" (note: lateral reflects Leads I, V4 & V5 & inferior reflects aVF) Recommend Review.	Ostman-Smith I, Wettrell G, Keeton B, Riesenfeld T, Holmgren D, Ergander U. Echocardiographic and electrocardiographic identification of those children with hypertrophic cardiomyopathy who should be considered at high-risk of dying suddenly. Cardiol Young. 2005 Dec;15(6):632-42. Montgomery JV, Harris KM, Casey SA, Zenovich AG, Maron BJ.. Relation of electrocardiographic patterns to phenotypic expression and clinical outcome in hypertrophic cardiomyopathy. Am J Cardiol2005 Jul 15;96(2):270-5. Furuki M, Hawai K, OnishiT, Hirata T. Value of Convex-Type ST-Segment Elevation and Abnormal Q Waves for ECG-Based Identification of Left Ventricular Remodeling in HCM. Kobe J. Med. Sci.,2009. 55, E16-E29. Konno T, Shimizu M, Ino H, et al. Diagnostic value of abnormal Q waves for identification of preclinical carriers of HCM based on a molecular genetic diagnosis. European Heart Journal 2004 25, 246–251

CAD Q-Waves	Q-Waves diagnostic of Coronary Artery Disease Age ≥ 40 AND No WPW AND NO LBBB AND V5: Q amp / R amp > 0.13 AND Q Area Ratio < -.62 aVF: Q Area Ratio < -1.5 V2: |Max negative| > |Max positive| (predominantly negative) AND Q Integral / (Max amp – Q amp) < -1.0 Note: Q Area Ratio is the (100 * Q integral) / [QRS duration x (Max amp – Q amp)] ; (Q integral and Q amp are negative) "**Diagnostic Q-Waves: Lateral Inferior Anterior**" (note: lateral, inferior and anterior reflect V5, aVF and V2 – added / removed as appropriate) Recommend Review.	Prognostic value of electrocardiographic detection of unrecognized myocardial infarction in persons with stable coronary artery disease: data from the Heart and Soul Study. Kehl D, Farzaneh-Far R, Na B and Whooley M. Clinical Research In Cardiology 2011:100:359-366, DOI: 10.1007/s00392-010-0255-2 Zhang Z, Prineas R, Eaton C. Evaluation and Comparison of the Minnesota Code and Nova code for Electrocardiographic Q-ST Wave Abnormalities for the Independent Prediction of Incident Coronary Heart Disease and Total Mortality (from the Women's Health Initiative). American Journal Cardiology. 2010:106;18-25.ISSN0002-149,0.1016/j.amjcard.2010.02.007.
Sx Rx Asymmetry	Asymmetry in V5 In Lead V5: |S amp| > R amp "**Asymmetry: Sx > Rx**" Report.	
ARVD	Arrhythmogenic Right Ventricular Dysplasia Lead V2 Upstroke time from nadir of S to end of S > 55 msec AND T amp in V2 < -100 µV "**ARVD S Upstroke in Z: XX msec**" Report. Note: See T-Wave inversion - may trigger Recommend Review	Nasir K, Bomma C, Tandri H, et al. Electrocardiographic features of arrhythmogenic right ventricular dysplasia/cardiomyopathy according to disease severity: a need to broaden diagnostic criteria. Circulation. 2004 Sep 21;110(12):1527-34. Marcus FI, McKenna WJ, Sherrill D, et al. Diagnosis of arrhythmogenic right ventricular cardiomyopathy / dysplasia: proposed modification of the Task Force Criteria. Eur Heart J. 2010 Apr;31(7):806-14. Epub 2010 Feb 19.

T-Wave Inversion	T-Wave Inversion: Lateral (Leads I, V4 or V5): T amp < -100 µV AND NO LBBB Inferior (Lead aVF): T amp < -100 µV AND NO LBBB Anterior (Leads V2 or V3): T amp < -100 µV AND NO LBBB AND NO (RBBB OR icRBBB) AND NOT(Female AND Age < 25) "**T-wave inversion: Lateral Inferior Anterior**" Note: Labels **Lateral**, **Inferior** &/or **Anterior** are removed when normal. Recommend Review.	Mandic S, Fonda H, Dewey F, Le VV, Stein R, Wheeler M, Ashley EA, Myers J, Froelicher VF. Effect of gender on computerized electrocardiogram measurements in college athletes. Phys Sports med. 2010 Jun;38(2):156-64. PubMed PMID: 20631475.
RVH	Right Ventricular Hypertrophy QRS duration ≤ 120 msec AND R in V2 > 700 µV AND R/S ratio in V2 > 1 (S ≠ 0) AND R amp in V2 + S amp in V5 > 1050 µV AND Age ≥ 30 OR Age < 30 AND RAA OR T-Wave Inverse in V2 OR RAD "**RVH Rz: XX µVolts Sz: YY µVolts**" Recommend Review.	Lehtonen J, Sutinen S, Ikäheimo M, Pääkkö P. Electrocardiographic criteria for the diagnosis of right ventricular hypertrophy verified at autopsy. Chest. 1988 Apr;93(4):839-42. Surawicz B. Electrocardiographic diagnosis of chamber enlargement. J Am CollCardiol. 1986 Sep;8(3):711-24.
Low Voltage	Low QRS Voltage QRS Vector Mag < 550 µV "**Low QRS Voltage - QRS Vector Magnitude: XX µVolts**" Report.	Marcus FI, McKenna WJ, Sherrill D,et al. Diagnosis of arrhythmogenic right ventricular cardiomyopathy / dysplasia: proposed modification of the Task Force Criteria. Eur Heart J. 2010 Apr;31(7):806-14. Epub 2010 Feb 19. Seward JB, Casaclang-Verzosa G. Infiltrative cardiovascular diseases: cardiomyopathies that look alike. J Am CollCardiol. 2010 Apr 27;55(17):1769-79.

Brugada	Brugada – Type 1 ST in V2 > 200 µV AND ST segment is down-sloping AND QRS duration > 100 msec AND T in V2 < -100 µV **"Brugada ST in V2: XX µVolts"** Recommend Review.	Junttila MJ, Raatikainen MJ, Karjalainen J, et al. Prevalence and prognosis of subjects with Brugada-type ECG pattern in a young and middle-aged Finnish population. Eur Heart J. 2004 May;25(10):874-8.
ST Depression	ST Depression as measured in Lead V5 ST Average from end of S to S + 80 msec < -50 µV AND No LBBB **"ST Depression in V5: XX µVolts"** Recommend Review.	Haghjoo M, Mohammadzadeh S, Taherpour M, et al. ST-segment depression as a risk factor in hypertrophic cardiomyopathy. Europace. 2009 May;11(5):643-9. Epub 2009 Jan 22.
ST Elevation	ST Elevation at j-point: ST_{V5} > 200 µV ST_{aVF} > 200 µV ST_{V2} > 300 µV **"ST Elevation: V5 & aVF & V2"** Note: Leads added / removed as appropriate. Report.	Macfarlane PW. Age, Sex, and the ST Amplitude in Health and Disease. Journal of Electrocardiology2001; 34:235-241. Leo T, Uberoi A, Jain NA, Garza D, et al. The impact of ST elevation on athletic screening. Clin J Sport Med. 2011 Sep;21(5):433-40.

Long QT	Long QT interval, adjusted for HR using Bazett correction (QTc) QRS Duration < 128 msec AND Male: QTc > 470 msec Female: QTc > 480 **"Possible Long QT Syndrome: XX msec (QTc)"** Report. QRS Duration < 128 msec AND QTc > 500 **"Long QT Syndrome: XX msec (QTc)"** Recommend Review. Note: See Preferences 5.1.2.5 – User may select Bazett or Hodges. Hodges is the default. Bazett: QTc = QT / SQRT(60/HR) Hodges: QTc = QT + 1.75*(HR-60) in msec	Basavarajaiah S, Wilson M, Whyte G, et al. Prevalence and significance of an isolated long QT interval in elite athletes. Eur Heart J. 2007;28(23):2944-9. Turkmen M, Barutcu I, Esen AM, et al. Assessment of QT interval duration and dispersion in athlete's heart. J Int Med Res. 2004;32(6):626-32 http://biostat.mc.vanderbilt.edu/wiki/Main/ECGPredictionInterval
Positive T in aVR	Positive T wave in Lead aVR T amp in aVR > 0 **"Positive T-Wave in aVR: XX µVolts"** Report.	Tan SY, Engel G, Myers J, et. Al. The Prognostic Value of T Wave Amplitude in Lead aVR in Males. Ann Noninvasive Electrocardiol. 2008 Apr;13(2):113-9.

RL Reversal	Lead I Right-Left reversal of leads QRS - T Correlation between Lead I an V5 < -0.4 Recommend User verify correct lead placement: **"Possible RA/LA Reversal"**
Pacemaker Detected	Detected pacemaker pulses associated with the onset of P or QRS shall trigger a Pacemaker Detected finding. All other diagnostic ECG findings shall be removed and the legend **"Pacemaker Detected - Automatic Interpretation NOT Valid"** added.
Patient Age	If the patient age is less than the Intended Use age (age < 14) then the system shall add a legend to the ECG stating: **"Patient age is less than the Intended Usage age".**