

CARDIAC INSIGHT, INC.

Cardea 20/20™ ECG Interpretation Criteria

CARDEA 20/20™ **ECG**

Resting ECG Analysis System

Model CS-2020

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1 Introduction

1.1 Indications for Use

Cardea 20/20 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.

Cardea 20/20 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.

1.2 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.

1.3 Contraindications

- Cardea 20/20 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 known to be associated with increased patient risk. The detection of any of these conditions in a patient ECG triggers a legend displayed by the Cardea 20/20 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	<p>The system shall determine the average Heart Rate (HR)</p> <p>HR > 95: "High HR: XX Recommend re-test after resting"</p> <p>HR < 30: "Bradycardia HR: XX" and Recommend Review.</p>	<p>Yusuf, S. and Camm, A. J. Deciphering the sinus tachycardias. Clinical Cardiology, 2005; 28: 267–276. doi: 10.1002/clc.4960280603</p>
RAA	<p>Right Atrial Abnormality</p> <p>P wave amplitude in V5, aVF or V2 > 250 μV</p> <p>"RAA lead: XX μVolts" Recommend Review.</p>	<p>Kaykha A, Myers J, Dessser KB, et al. The prognostic importance of isolated P-Wave abnormalities. Clin Cardiol. 2010 Jun;33(6):E87-93. PubMed PMID: 20552614.</p>
LAA	<p>Left Atrial Abnormality</p> <p>V1 \leq -100 μV AND area of negative pulse > 46 mm-msec AND P-wave terminates in a negative phase.</p> <p>"LAA V1: XX μVolts, Area: YY mm-msec" Recommend Review.</p>	<p>Kaykha A, Myers J, Dessser KB, et al. The prognostic importance of isolated P-Wave abnormalities. Clin Cardiol. 2010 Jun;33(6):E87-93. PubMed PMID: 20552614.</p>
Flutter	<p>Atrial Flutter</p> <p>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.</p> <p>NOTE: Respiration causes rhythmic increases and decreases of HR. The RR standard deviation should be computed after the removal of rhythmic variability.</p> <p>"Atrial Flutter" Recommend Review.</p>	

Diagnostic Condition	Requirement and Device Response	Clinical References
A.Fib	<p>Atrial Fibrillation</p> <p>No P-waves AND RR standard deviation > 15%.</p> <p>"Atrial Fibrillation" Recommend Review.</p>	
Pause	<p>Atrial Pause</p> <p>RR interval > 40% of the average RR intervals.</p> <p>"Atrial Pause" Report.</p>	
PAC	<p>Premature Atrial Contraction</p> <p>RR interval < 60% of the average RR intervals.</p> <p>"Premature Atrial Contraction" Report.</p>	
Erratic HR	<p>Erratic Heart rate</p> <p>RR standard deviation > 15% and NOT Flutter</p> <p>"Erratic Sinus" Report.</p>	
Long PR	<p>Time interval between the onset of P and the isoelectric (Q) point.</p> <p>PR > 300 msec.</p> <p>"Anomalous PR Interval: XX msec" Recommend Review.</p>	<p>Pfeufer A, van Noord C, Marciante K et al. Genome-wide association study of PR interval. Nat Genet. 2010 Feb;42(2):153–159. https://doi.org/10.1038/ng.517</p> <p>Ramirez AH, Schildcrout JS, Blakemore DL et al. Modulators of normal ECG intervals identified in a large electronic medical record. Heart Rhythm. 2011 Feb;8(2):271–277. https://doi.org/10.1016/j.hrthm.2010.10.034</p>

Diagnostic Condition	Requirement and Device Response	Clinical References
Long QRS	QRS duration > 125 msec "QRS Dur: XX msec" Recommend Review.	<p>Desai AD, Yaw TS, Yamazaki T, et al. Prognostic Significance of Quantitative QRS Duration. Am J Med. 2006 Jul;119(7):600–606. https://doi.org/10.1016/j.amjmed.2005.08.028</p> <p>Bongioanni S, Bianchi F, Migliardi A, et al. Relation of QRS duration to mortality in a community-based cohort with hypertrophic cardiomyopathy. Am J Cardiol. 2007 Aug 1;100(3):503–506. https://doi.org/10.1016/j.amjcard.2007.03.049</p>

Diagnostic Condition	Requirement and Device Response	Clinical References
Ectopy	<p>Narrow Ectopic Beats:</p> <p>Non-dominant beat with QRS > dominant beat ≤ 120 msec.</p> <p>"Ectopy present - QRS Duration: XX" Report.</p> <p>Wide Ectopic Beats:</p> <p>Wide Complex Ectopy: Non-dominant beat(s) having a QRS duration > 120 msec.</p> <p>Single beat: "Wide complex ectopy present - QRS Duration: XX" Report.</p> <p>Two or more: "Wide complex ectopy present - QRS Duration: XX" Recommend Review.</p> <p>Polymorphic Wide Complex Ectopy: Two or more wide complex non-dominant beats associated with different beat classes (i.e. not the same morphology)</p> <p>"Polymorphic wide complex ectopy present" Recommend Review.</p>	<p>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.</p>

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

Diagnostic Condition	Requirement and Device Response	Clinical References
LBBB	<p>Left Bundle Branch Block</p> <p>(A):</p> <p>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</p> <p>Or (B):</p> <p>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)]</p> <p>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.</p> <p>"LBBB" Recommend Review.</p>	<p>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</p> <p>Breithardt G and Breithardt O. Left Bundle Branch Block, an Old–New Entity. Open Jour Cardiovasc. Trans. Res. 2012; 5:107–11</p>

Diagnostic Condition	Requirement and Device Response	Clinical References
RBBB	<p>Right Bundle Branch Block</p> <p>(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</p> <p>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</p> <p>"RBBB" Recommend Review: QRS Dur ≥ 120 msec Report: QRS Dur < 120 msec</p>	<p>Kim J, Noseworthy P, McCarty D, et al. Significance of Electrocardiographic Right Bundle Branch Block in Trained Athletes. Am J Cardiol. 2011;107(7):1083–1089. https://doi.org/10.1016/j.amicard.2010.11.037</p> <p>Peters S, Trümmel M, Koehler B. Special features of right bundle branch block in patients with arrhythmogenic right ventricular cardiomyopathy/dysplasia. Int J Cardiol. 2012 May 17;157(1):102–103. https://doi.org/10.1016/j.ijcard.2011.09.070</p>

Diagnostic Condition	Requirement and Device Response	Clinical References
icRBBB	<p>Incomplete Right Bundle Branch Block</p> <p>(A): QRS duration < 110 msec AND S duration > 20 msec in V5 AND RSR' waveform in V2 AND Not RBBB AND NO WPW</p> <p>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)</p> <p>"ICRBBB" Report.</p>	
WPW	<p>Wolff, Parkinson, White</p> <p>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</p> <p>"WPW" Recommend Review.</p>	<p>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).</p> <p>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 Coll Cardiol. 2003 Jan 15;41(2):239-44.</p>

Diagnostic Condition	Requirement and Device Response	Clinical References
HCM Q-Waves	<p>Q-Waves diagnostic of HCM in Leads I, V4, V5 or aVF</p> <p>Age < 40 AND No WPW AND NO LBBB AND (Q amp < -350 μV OR Q duration \geq 40 msec)</p> <p>"Diagnostic Q-Waves: Lateral Inferior" (note: lateral reflects Leads I, V4 & V5 & inferior reflects aVF) Recommend Review.</p>	<p>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. <i>Cardiol Young</i>. 2005 Dec;15(6):632-42.</p> <p>Montgomery JV, Harris KM, Casey SA, Zenovich AG, Maron BJ.. Relation of electrocardiographic patterns to phenotypic expression and clinical outcome in hypertrophic cardiomyopathy. <i>Am J Cardiol</i> 2005 Jul 15;96(2):270-5.</p> <p>Furuki M, Hawai K, Onishi T, Hirata T. Value of Convex-Type ST-Segment Elevation and Abnormal Q Waves for ECG-Based Identification of Left Ventricular Remodeling in HCM. <i>Kobe J. Med. Sci.</i>, 2009. 55, E16-E29.</p> <p>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. <i>European Heart Journal</i> 2004 25, 246–251</p>

Diagnostic Condition	Requirement and Device Response	Clinical References
CAD Q-Waves	<p>Q-Waves diagnostic of Coronary Artery Disease</p> <p>Age ≥ 40 AND No WPW AND NO LBBB AND</p> <p>V5: Q amp / R amp > 0.13 AND Q Area Ratio $< -.62$</p> <p>aVF: Q Area Ratio < -1.5</p> <p>V2: $\text{Max negative} > \text{Max positive}$ (predominantly negative) AND Q Integral / (Max amp – Q amp) < -1.0</p> <p>Note: Q Area Ratio is the $(100 * \text{Q integral}) / [\text{QRS duration} \times (\text{Max amp} - \text{Q amp})]$; (Q integral and Q amp are negative)</p> <p>“Diagnostic Q-Waves: Lateral Inferior Anterior” (note: lateral, inferior and anterior reflect V5, aVF and V2 – added / removed as appropriate) Recommend Review.</p>	<p>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</p> <p>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.</p>
Sx Rx Asymmetry	<p>Asymmetry in V5</p> <p>In Lead V5: $\text{S amp} > \text{R amp}$</p> <p>“Asymmetry: Sx > Rx” Report.</p>	

Diagnostic Condition	Requirement and Device Response	Clinical References
ARVD	<p>Arrhythmogenic Right Ventricular Dysplasia</p> <p>Lead V2 Upstroke time from nadir of S to end of S > 55 msec AND T amp in V2 < -100 μV</p> <p>"ARVD S Upstroke in Z: XX msec"</p> <p>Report.</p> <p>Note: See T-Wave inversion - may trigger Recommend Review</p>	<p>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.</p> <p>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.</p>
T-Wave Inversion	<p>T-Wave Inversion:</p> <p>Lateral (Leads I, V4 or V5): T amp < -100 μV AND NO LBBB</p> <p>Inferior (Lead aVF): T amp < -100 μV AND NO LBBB</p> <p>Anterior (Leads V2 or V3): T amp < -100 μV AND NO LBBB AND NO (RBBB OR icRBBB) AND NOT(Female AND Age < 25)</p> <p>"T-wave inversion: Lateral Inferior Anterior" Note: Labels Lateral, Inferior &/or Anterior are removed when normal. Recommend Review.</p>	<p>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.</p>

Diagnostic Condition	Requirement and Device Response	Clinical References
RVH	<p>Right Ventricular Hypertrophy</p> <p>QRS duration \leq 120 msec AND R in V2 $>$ 700 μV AND R/S ratio in V2 $>$ 1 (S \neq 0) AND R amp in V2 + S amp in V5 $>$ 1050 μV AND</p> <p>Age \geq 30 OR Age $<$ 30 AND RAA OR T-Wave Inverse in V2 OR RAD</p> <p>"RVH Rz: XX μVolts Sz: YY μVolts" Recommend Review.</p>	<p>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.</p> <p>Surawicz B. Electrocardiographic diagnosis of chamber enlargement. J Am CollCardiol. 1986 Sep;8(3):711-24.</p>
Low Voltage	<p>Low QRS Voltage</p> <p>QRS Vector Mag $<$ 550 μV</p> <p>"Low QRS Voltage - QRS Vector Magnitude: XX μVolts" Report.</p>	<p>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.</p> <p>Seward JB, Casaclang-Verzosa G. Infiltrative cardiovascular diseases: cardiomyopathies that look alike. J Am CollCardiol. 2010 Apr 27;55(17):1769-79.</p>
Brugada	<p>Brugada – Type 1</p> <p>ST in V2 $>$ 200 μV AND ST segment is down-sloping AND QRS duration $>$ 100 msec AND T in V2 $<$ -100 μV</p> <p>"Brugada ST in V2: XX μVolts" Recommend Review.</p>	<p>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.</p>

Diagnostic Condition	Requirement and Device Response	Clinical References
ST Depression	<p>ST Depression as measured in Lead V5</p> <p>ST Average from end of S to S + 80 msec < -50 µV AND No LBBB</p> <p>"ST Depression in V5: XX µVolts" Recommend Review.</p>	<p>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.</p>
ST Elevation	<p>ST Elevation at j-point:</p> <p>ST_{V5} > 200 µV ST_{aVF} > 200 µV ST_{V2} > 300 µV</p> <p>"ST Elevation: V5 & aVF & V2" Note: Leads added / removed as appropriate. Report.</p>	<p>Macfarlane PW. Age, Sex, and the ST Amplitude in Health and Disease. Journal of Electrocardiology 2001; 34:235-241.</p> <p>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.</p>
Long QT	<p>Long QT interval, adjusted for HR using Bazett correction (QTc)</p> <p>QRS Duration < 128 msec AND Male: QTc > 470 msec Female: QTc > 480</p> <p>"Possible Long QT Syndrome: XX msec (QTc)" Report.</p> <p>QRS Duration < 128 msec AND QTc > 500</p> <p>"Long QT Syndrome: XX msec (QTc)" Recommend Review.</p> <p>Note: See Preferences 5.1.2.5 – User may select Bazett or Hodges. Hodges is the default.</p> <p>Bazett: QTc = QT / SQRT(60/HR) Hodges: QTc = QT + 1.75*(HR-60) in msec</p>	<p>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):2944–2949. https://doi.org/10.1093/eurheartj/ehm404</p> <p>Turkmen M, Barutcu I, Esen AM, et al. Assessment of QT interval duration and dispersion in athlete's heart. J Int Med Res. 2004 Nov–Dec;32(6):626–632. https://doi.org/10.1177/147323000403200607</p>

Diagnostic Condition	Requirement and Device Response	Clinical References
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" .	